DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 153, 154, 155, 156, 157, and 158

[CMS–9930–F]

RIN 0938–AT12

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019

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 and risk adjustment data validation programs; cost-sharing parameters; and user fees for Federally-facilitated Exchanges and State Exchanges on the Federal platform. It finalizes changes that provide additional flexibility to States to apply the definition of essential health benefits (EHB) to their markets, enhance the role of States regarding the certification of qualified health plans (QHPs); and provide States with additional flexibility in the operation and establishment of Exchanges, including the Small Business Health Options Program (SHOP) Exchanges. It includes changes to standards related to Exchanges; the required functions of the SHOPs; actuarial value for stand-alone dental plans; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions; and other related topics.

DATES: *Effective Date:* These regulations are effective on June 18, 2018.

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
II. Background
A. Legislative and Regulatory Overview
B. Stakeholder Consultation and Input
C. Structure of Final Rule
III. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments
A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets
B. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act
C. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review Requirements
D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act
E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges
F. Part 157—Employer Interactions With Exchanges and SHOP Participation
G. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements
IV. Collection of Information Requirements
A. Wage Estimates
B. ICRs Regarding State Flexibility for Risk Adjustment
C. ICRs Regarding Risk Adjustment Data Validation
D. ICRs Regarding Health Insurance Issuer Rate Increases: Disclosure and Review Requirements—Applicability
E. ICRs Regarding Rate Increases Subject To Review
F. ICRs Regarding the Small Business Health Options Program
G. ICRs Regarding Essential Health Benefits
H. ICRs Regarding Medical Loss Ratio
I. Summary of Annual Burden Estimates for Final Requirements
J. Submission of PRA-Related Comments
V. Regulatory Impact Analysis
A. Statement of Need
B. Overall Impact
C. Impact Estimates of the Payment Notice Provisions and Accounting Table
D. Regulatory Alternatives Considered
E. Regulatory Flexibility Act
F. Unfunded Mandates
G. Federalism
H. Congressional Review Act
I. Reducing Regulation and Controlling Regulatory Costs

I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges'' (also called ''Marketplaces'') are entities established under the Patient Protection and Affordable Care Act (PPACA) through which qualified individuals and qualified employers can purchase health insurance coverage. Many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums, and receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The PPACA also established the risk adjustment program, which is intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets, both on and off Exchanges.

Over time, issuer exits and increasing insurance premiums have threatened the stability of the individual and small group Exchanges in many geographic areas. In previous rulemaking, we established provisions and parameters to implement many PPACA provisions and programs. In this final rule, we amend these provisions and parameters, with a focus on enhancing the role of States in these programs and providing States with additional flexibilities, reducing unnecessary regulatory burden

on stakeholders, empowering consumers, and improving affordability.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies with authorities and responsibilities under the PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. In this rule, within the limitations of the current statute, we are finalizing policies to reduce fiscal and regulatory burdens across different program areas, and to support innovative health insurance models.

We are finalizing several changes that would significantly expand the role of States in the administration of the PPACA. We received comments on additional ways to support State Exchanges (SBEs) in adopting innovative approaches to operating and sustaining their Exchanges, and to make the State Exchange on the Federal platform (SBE–FP) model a more appealing and viable model for States. We finalize policies under which States assume a larger role in reviewing the QHP certification standards of network adequacy and essential community providers for the Federally-facilitated Exchanges (FFEs). This will confirm States' traditional role in overseeing their health insurance markets, and reduce the issuer burden associated with having to comply with duplicative State and Federal reviews.

This rule also finalizes several policies that will provide States with greater flexibility. For example, this rule provides States with additional flexibility in applying the definition of EHBs to their markets starting with the 2020 plan year. In addition to granting States more flexibility regulating their markets, we believe this change would permit States to modify EHBs to increase affordability of health insurance in the individual and small group markets. This rule also provides States with significantly more flexibility in how they operate a Small Business Health Options Program (SHOP), permitting them to operate these Exchanges more efficiently, and therefore benefitting States, issuers, employers, and employees. These changes would allow for a more efficient SHOP, such that employers and employees could enroll in SHOP coverage by working with a QHP issuer or SHOP-registered agent or broker. Additionally, the finalized policies provide States more flexibility regarding risk adjustment transfers in their markets. We also make it easier for States to apply for and be granted an adjustment to the individual market medical loss ratio (MLR) standard in their State. We believe this change provides States with an additional tool to help stabilize, innovate and provide relief in their individual markets. Additionally, we make other changes to the MLR program to reduce the burden on issuers.

Risk adjustment continues to be a core program for stabilizing the individual and small group markets both on and off Exchanges, and we are finalizing recalibrated parameters for the HHS risk adjustment methodology. We are also finalizing several changes related to the risk adjustment data validation program that are intended to ensure the integrity of the results of risk adjustment, while alleviating issuer burden.

As we do every year in the HHS notice of benefit and payment parameters final rule, we are finalizing updated parameters applicable in the individual and small group markets. We are finalizing the user fee rate for issuers participating on FFEs and SBE–FPs for 2019 to be 3.5 and 3.0 percent of premiums, respectively. We are finalizing the premium adjustment percentage for 2019, which is used to set the rate of increase for several parameters detailed in the PPACA, including the maximum annual limitation on cost sharing for 2019, the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Internal Revenue Code of 1986 (the Code), and the assessable payment amounts under section 4980H(a) and (b) of the Code. We are finalizing updates to the maximum annual limitations on cost sharing for the 2019 benefit year for cost-sharing reductions plan variations.

We are finalizing a number of changes related to rate review that are intended to reduce regulatory burden on States and issuers in regard to the rate filing process. Specifically, we are exempting student health insurance coverage from Federal rate review requirements, beginning with coverage effective on or after July 1, 2018. We are also modifying the 10 percent threshold for reasonableness review to a 15 percent default threshold.

Recognizing that Exchanges, including the FFEs, face resource constraints, we are changing the requirements regarding Navigators, and the requirements regarding non-Navigator assistance personnel subject to § 155.215, to enable Exchanges to more easily operate these programs with limited resources. Similarly, we are allowing an agent, broker or issuer participating in direct enrollment to have its selected third-party entity conduct operational readiness reviews, rather than requiring that those reviews be conducted by entities approved by HHS.

We also finalize relatively minor adjustments to our programs and rules as we do each year in the HHS notice of benefit and payment parameters. We are finalizing a number of incremental amendments to our policies around coverage, eligibility, enrollment, and affordability exemptions.

We continue to be very interested in exploring ways to improve Exchange program integrity. In the proposed rule, we sought comment on a number of program integrity items, including whether we should consider shortening the length of time the Exchanges are authorized to obtain enrollee tax information, as well as ways to prompt more timely consumer reporting of changes in circumstances during the benefit year that may impact an individual's eligibility for coverage and financial assistance. In addition, we requested comment on any additional program integrity improvements that were not outlined in the proposed rule, but could be beneficial in a future rulemaking.

Finally, as noted in the proposed rule, we intend to consider proposals in future rulemaking that would help reduce drug costs and promote drug price transparency. We also intend to provide guidance on other aspects of Exchange eligibility in the near future. In particular, we intend to reconsider the appropriate thresholds for changes in income that will trigger a data matching inconsistency, processes for denying eligibility for advance subsidies for individuals who fail to reconcile advance payments of the premium tax credit (APTC) on their Federal income tax return, processes for matching enrollment data with the Medicare and Medicaid programs in order to help consumers avoid duplicate enrollments, and the appropriate manner of recalculating APTC following a midyear change in eligibility, and sought comments on each of these issues as we prepare rulemaking on these topics.

Instituting strong program safeguards to ensure that only individuals who are eligible are enrolled in Exchange coverage, and that they are only

receiving the amount of financial assistance for which they are eligible, is essential to ensuring that the Exchanges operate as intended, and is also a key priority for the Administration. We have already taken action to strengthen safeguards around Exchange eligibility, most recently through the implementation of pre-enrollment verification for special enrollment periods; however, we continue to be interested in exploring ways to further safeguard Federal tax dollars flowing through Exchanges.

II. Background

A. Legislative and Regulatory Overview

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

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

Section 2701 of the PHS Act, as added by the PPACA, 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. These factors are family size, rating area, age and tobacco use.

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

Section 2702 of the PHS Act, as added by the PPACA, 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.[1]

Section 2703 of the PHS Act, as added by the PPACA, and sections 2712 and 2741 of the PHS Act, as added by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) prior to the enactment of the PPACA, 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 PPACA, generally requires health insurance issuers to submit an annual MLR report to HHS, and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 2794 of the PHS Act, as added by the PPACA, 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.''[2] 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 specifies that beginning with plan years starting in 2014, the Secretary, in conjunction with the States, will monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

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

Section 1302 of the PPACA provides for the establishment of an EHB package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value requirements. The law directs that EHBs be equal in scope to the benefits provided under 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 PPACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the PPACA, including coverage of the services described in section 1302(b) of the PPACA, to adhere to the cost-sharing limits described in section 1302(c) of the PPACA and to meet the AV levels established in section 1302(d) of the PPACA. 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 health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the PPACA.

Section 1302(d) of the PPACA describes the various levels of coverage based on actuarial value (AV). Consistent with section 1302(d)(2)(A) of the PPACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the PPACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the PPACA directs that the Small Business Health Options Program assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Sections 1312(f)(1) and (2) of the PPACA define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the PPACA, beginning in 2017, States have the option to allow issuers to offer QHPs in the large group market through an Exchange.[3] Section 1312(a)(2) of the PPACA provides that in a SHOP, a qualified employer may select a level of coverage, and that employees may then, in turn, choose SHOP plans within the level selected by the qualified employer.

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

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

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

Section 1311(c)(1)(B) of the PPACA 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 PPACA requires the Secretary to continue to operate, maintain, and update the internet portal developed under section 1103 of the PPACA to provide information to consumers and small businesses on affordable health insurance coverage options.

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

Section 1311(c)(6)(C) of the PPACA establishes special enrollment periods and section 1311(c)(6)(D) of the PPACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

Section 1312(e) of the PPACA 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 PPACA 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 PPACA. Section 1321(a)(1) of the PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the PPACA with respect to, among other things, the establishment and operation of Exchanges.

Sections 1313 and 1321 of the PPACA 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 PPACA provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

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

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

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

Section 1343 of the PPACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, funded by payments from those that attract lower-risk populations; thereby, reducing incentives for issuers to avoid higher-risk enrollees.

Section 1402 of the PPACA provides 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. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 5000A of the Code, as added by section 1501(b) of the PPACA, requires all applicable individuals to maintain minimum essential coverage (MEC) for each month or make an individual shared responsibility payment. Section 5000A(f) of the Code defines MEC as any of the following: (1) Coverage under a specified government sponsored program; (2) coverage under an eligible employer-sponsored plan; (3) coverage under a health plan offered in the individual market within a State; and (4) coverage under a grandfathered health plan. In addition, the HEALTHY KIDS Act amended section 5000A(f)(1)(A)(iii) of the Code to include in the definition of MEC CHIP look-alike plans, which are CHIP buy-in programs that provide benefits that are at least identical to the benefits provided by the title XXI CHIP program.[4] Section 5000A(f)(1)(E) of the Code authorizes the Secretary of HHS, in coordination with the Secretary of the Treasury, to designate other health benefits coverage as MEC. Under tax reform legislation that was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018.[5]

The Protecting Affordable Coverage for Employees Act (Pub. L. 114–60) amended section 1304(b) of the PPACA and section 2791(e) of the PHS Act to amend the definition of small employer in these statutes to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. It also amended these statutes to make conforming changes to the definition of large employer, and to provide that a State may treat as a small employer, with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.

1. Premium Stabilization Programs[6]

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409).

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published

[4] Public Law 115–120, 101 (2018).

[5] Public Law 115–97, 131 Stat. 2054.

[6] By ''premium stabilization programs,'' we are referring to the risk adjustment, risk corridors and reinsurance programs established by the PPACA.

the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743).

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

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).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the risk adjustment data validation process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the ''first Program Integrity Rule'' published in the August 30, 2013 **Federal Register** (78 FR 54069) and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045).

3. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and SHOP, 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 additional standards for SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second Program Integrity Rule. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

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

In an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058). In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification.

4. Essential Health Benefits and Actuarial Value

On December 16, 2011, HHS released a bulletin [7] (the EHB Bulletin) that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. HHS also published a bulletin that outlined its intended regulatory approach to calculations of AV on February 24, 2012.[8] 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). In the April 18, 2017 Market Stabilization final rule (82 FR 18346), we expanded the de minimis range applicable to plan metal levels.

5. Minimum Essential Coverage

In the February 1, 2013 **Federal Register** (78 FR 7348), we published a proposed rule that designates other health benefits coverage as MEC and outlines substantive and procedural requirements that other types of coverage must fulfill in order to be recognized as MEC. The provisions were finalized in the July 1, 2013 **Federal Register** (78 FR 39494).

In the November 26, 2014 **Federal Register** (79 FR 70674), we published a proposed rule seeking comments on whether State high risk pools should be permanently designated as MEC or whether the designation should be time-limited. In the February 27, 2015 **Federal Register** (80 FR 10750), we designated State high risk pools established on or before November 26, 2014 as MEC.

6. 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). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and

[7] ''Essential Health Benefits Bulletin.'' December 16, 2011. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

[8] ''Actuarial Value and Cost-Sharing Reductions Bulletin.'' February 24, 2012. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/Av-csr-bulletin.pdf.*

guaranteed renewability. In the April 18, 2017 Market Stabilization final rule (82 FR 18346), we released further guidance related to guaranteed availability.

7. 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 30239), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203) and the December 22, 2016 **Federal Register** (81 FR 94058).

8. Medical Loss Ratio

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The medical loss ratio 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), the March 8, 2016 **Federal Register** (81 FR 12203), and the December 22, 2016 **Federal Register** (81 FR 94183).

B. Stakeholder Consultation and Input

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

HHS also received several thousand unique comments in response to a request for information, entitled ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act and Improving Healthcare Choices to Empower Patients'', published in the June 12, 2017 **Federal Register** (82 FR 26885) (Request for Information). We anticipate continuing to address comments in future rulemaking and guidance.

C. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 147, 153, 154, 155, 156, 157, and 158.

The final regulations in part 147 amend the rules regarding fair health insurance premiums and guaranteed availability to reflect final changes related to the SHOPs and special enrollment periods.

In connection with part 153, we are recalibrating the risk adjustment models consistent with the methodology finalized for the 2018 benefit year with slight modifications to the drug classes included in the 2019 benefit year adult models and the incorporation of blended MarketScan® and the most recent enrollee-level External Data Gathering Environment (EDGE) data. This final rule addresses the high-cost risk pooling adjustment, where we are finalizing the same parameters that applied to the 2018 benefit year for the 2019 benefit year risk adjustment. The finalized provisions related to part 153 include the risk adjustment user fee and modifications to risk adjustment data validation. We also finalize a policy to provide States flexibility to request reductions in risk adjustment transfers in the small group market starting for the 2020 benefit year and beyond.

The final regulations in part 154 finalize certain modifications to reduce regulatory burden and enhance State flexibility for the rate review program. We are finalizing an exemption for student health insurance coverage from Federal rate review requirements. We are finalizing a proposal to raise the default threshold for review of reasonableness in the rate review process from 10 percent to 15 percent. We also are finalizing a proposal to allow States with Effective Rate Review Programs to set later submission deadlines for rate filings from issuers that offer non-QHPs only. In addition, we are finalizing the change to the notification period for States with Effective Rate Review Programs to provide advance notice to HHS prior to posting rate increases (from 30 days to 5 business days).

The final regulations in part 155 include modifications to the functions of an Exchange, and a new approach to operational readiness reviews for direct enrollment partners which will allow agents, brokers, and issuers to select their own third-party entities for conducting those reviews. We are finalizing modifications to the rules around verification of eligibility. We are also finalizing increased flexibility in the Navigator program by removing the requirement that each Exchange must have at least two Navigator entities, one of which must be a community and consumer focused non-profit, and by removing the standard requiring physical presence of the Navigator entity in the Exchange service area. We are modifying the parameters around certain special enrollment periods. We are modifying the effective date options for enrollee-initiated terminations, at the option of the Exchange, and amending the affordability exemption so that it may be based on the lowest cost Exchange plan if there is no bronze level plan sold through the Exchange in that rating area.

The final regulations in part 156 include changes to EHB and the QHP certification process. The final regulations in part 156 set forth parameters related to cost sharing, including the premium adjustment percentage, the maximum annual limitation on cost sharing, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2019. The regulations at part 156 also include finalized FFE and SBE–FP user fee rates for the 2019 benefit year for all issuers participating on the FFEs or SBE–FPs. The regulations at part 156 also include finalized policies related to actuarial value for stand-alone dental plans (SADPs).

The final amendments to the regulations in parts 155, 156, and 157 include finalized proposals that would provide SHOPs with additional operational flexibility, and would modify the requirements for issuers, employers, and employees interacting with SHOPs.

The final amendments to the regulations in part 158 include revisions related to reporting quality improvement activity expenses as part

of the formula for calculating MLR, and revisions related to State requests for adjustment to the individual market MLR standard.

III. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In the November 2, 2017 **Federal Register** (82 FR 51052), we published the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019'' proposed rule (proposed 2019 Payment Notice or proposed rule). We received 416 comments, including 99 comments that were substantially similar to one of four different letters, each regarding the proposals on EHBs, one addressing EHBs and the Navigator program, and one addressing proposals related to EHBs, Navigators, SHOPs and network adequacy. Comments were received from State entities, such as departments of insurance and State Exchanges; health insurance issuers; providers, both individuals and provider groups; consumer groups; industry 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.

Comment: We received multiple comments criticizing the short comment period, stating that the comment period made it difficult for stakeholders to conduct an in-depth analysis of the proposed rule. Commenters suggested that HHS adopt a comment period of at least 30 days from rule publication, and to fully comply with notice-and-comment requirements under the Administrative Procedure Act.

Response: The timeline for publication of this final rule accommodates issuer filing deadlines for the 2019 benefit year. A longer comment period would have delayed the publication of this final rule, and created significant challenges for States, Exchanges, issuers, and other entities in meeting deadlines related to implementing these rules. We will continue to try to expand the comment period for the annual HHS notice of benefit and payment parameters while also providing industry and other stakeholders with more time to implement the final rule.

Comment: We received some comments generally supportive of State flexibility, stating that by removing existing regulatory barriers, issuers will be able to offer a more diverse selection of coverage options that meet both the financial and health coverage needs of consumers while meeting various State needs.

Response: We agree that State flexibility with respect to oversight of State insurance markets is an important goal, and recognize the traditional role States have as the primary regulators of their insurance markets. States are best positioned to address the specific needs of their consumers, and may be better able than the Federal government to develop policies that are tailored to allow issuers in their State to develop plans that address both the needs and cost concerns of beneficiaries in their State.

Comment: We received numerous comments cautioning us about making changes that would weaken the PPACA. Some commenters expressed concern that the proposed changes would remove some of the protections afforded by the PPACA, such as the certainty of EHBs.

Response: Our top priority at HHS is putting consumers first. While we have made great strides forward, there is still work to be done, including ensuring that coverage is affordable to all consumers. We have already taken important steps to streamline our regulations and our operations with the goal of reducing unnecessary burden, increasing efficiencies and improving the consumer experience. Yet, we have recently seen how regulations intended to protect consumers can, instead, undermine consumers' access to affordable health coverage. In this final rule, we finalize policies that are intended to help control costs of coverage in order to make coverage more affordable for consumers, particularly unsubsidized consumers. We will continue to find innovative ways to reduce costs and burdens while meeting the health needs of all Americans. We are continuing to address feedback we receive from stakeholders and the public, and in turn we are making changes that will better serve consumers and allow States to address the unique health needs of their populations.

Comment: Commenters responded to our request for comment on ideas for future rulemaking about ways to help reduce drug costs and promote drug price transparency. All commenters acknowledged the consumer benefits of lowering drug costs and having more transparent drug pricing; however, commenters cautioned that any changes be done in a thoughtful manner, that considers value in addition to cost, with input from all stakeholders.

Response: We appreciate the ideas for future rulemaking and will consider these suggestions.

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

1. Fair Health Insurance Premiums (§ 147.102)

As discussed elsewhere in this final rule, we are finalizing substantial changes to the requirements applicable to SHOPs to provide those programs with the flexibility to operate in a leaner fashion, a flexibility that we intend to utilize in the Federally-facilitated Small Business Health Options Program (FF–SHOP). As part of these changes and, as discussed in the preamble to §§ 156.285 and 156.286, we proposed that, effective on the effective date of this rule, the requirement in § 156.285(a)(4)(ii) regarding premium rating standards in the FF–SHOPs would not apply for plan years beginning on or after January 1, 2018. Therefore, we proposed to delete from § 147.102(c)(3)(iii)(D) a reference to § 156.285(a)(4), and to replace the reference to FF–SHOPs with a reference to SHOPs generally, to reflect that, under the proposed approach for SHOPs, some SHOPs may want to prohibit issuers from offering average enrollee premiums.

We did not receive comments on this proposal, and are finalizing the change as proposed, with one minor typographical correction.

We also sought comment on whether issuers offering coverage through SHOPs should always be required to offer average enrollee premiums, or should be required to do so only if required under applicable State law.

Comment: Comments were mixed regarding whether issuers offering coverage through SHOPs should always be required to offer average enrollee premiums. One commenter stated that issuers offering coverage through SHOPs should always be required to offer average enrollee premiums, while others stated that issuers should be required to do so only if required by applicable State law. One of these commenters further recommended that average premium rating should be permitted only when a SHOP does not allow employees to choose plans among multiple issuers. The commenter stated that average enrollee premiums based

on employees selecting a particular plan could result in illogical rates, such as a richer plan having lower rates than a leaner plan because only younger employees selected the richer plan. Another commenter stated that all issuers, regardless of whether they are offering coverage on or off SHOP, should be allowed to offer average enrollee premiums.

Response: For purposes of consistency, we believe that issuers offering coverage through a SHOP should be permitted to offer average enrollee premiums to the same extent that issuers may do so off SHOP under existing State rules. Also, given the decrease in issuer participation in the FF–SHOPs, some SHOP employers only have one issuer offering FF–SHOP plans in their area and will not be able to offer their employers a choice of plans across issuers. In addition, historically, a majority of employers have not offered employee choice across different issuers, thus mitigating the risk of variance in average premium rates across plans. Therefore, we do not believe Federal guidance or regulation is currently warranted in this area. Thus, issuers offering coverage through a SHOP may offer average enrollee premiums to the extent required or permitted by the applicable State, and will not be required under Federal law to do so, unless required by the State.

2. Guaranteed Availability of Coverage (§ 147.104)

i. SHOP

As discussed elsewhere in this final rule, we proposed and are finalizing substantial changes to the requirements applicable to SHOPs to provide them with the flexibility to operate in a leaner fashion, a flexibility that we will utilize in the FF–SHOPs. Among those changes, effective on the effective date of this rule, the requirements in § 156.285 will apply for plan years starting before January 1, 2018. New § 156.286 specifies those requirements contained in § 156.285 that, effective on the effective date of this rule, will continue to apply for plan years starting on or after January 1, 2018. Among those requirements is the requirement in § 156.285(e) which permits a QHP offered in the SHOP to apply group participation rules under certain circumstances. This provision will be listed in new § 156.286(e). The marketwide regulations at § 147.104(b)(1)(i)(B) currently reference § 156.285(e), and we proposed to add a reference to § 156.286(e) to clarify that, effective on the effective date of this rule, for plan years that start on or after January 1, 2018, QHPs offered in the SHOP may restrict the availability of coverage, with respect to a group health plan that cannot comply with group participation rules, to an annual enrollment period of November 15 through December 15 of each calendar year. Because we are finalizing new § 156.286(e) as proposed, we are also finalizing the proposal to reference new § 156.286(e) in § 147.104(b)(1)(i)(B).

Comment: One commenter supported the proposal to add to § 147.104(b)(1)(i)(B) a reference to § 156.286(e). One commenter opposed permitting QHPs to restrict coverage availability when a group health plan cannot comply with group participation rules, while another commenter stated that an employer that fails to comply with such rules should not be afforded guaranteed availability of coverage, either generally or during an annual open enrollment period, either on or off-SHOP.

Response: As indicated in the section of the preamble discussing the SHOP rule, we are finalizing, as proposed, the proposal to add new § 156.286(e), which would apply, to plan years starting on or after January 1, 2018, the existing regulatory provision that allows QHPs offered in the SHOP to restrict the availability of coverage with respect to a group health plan that cannot comply with group participation rules, to an annual enrollment period of November 15 through December 15 of each calendar year. Thus, we are also finalizing the proposal to reference new § 156.286(e) in § 147.104(b)(1)(i)(B).

We also proposed, and are finalizing, the removal of the small group coverage effective dates that are found in the SHOP regulations at § 155.725 with respect to plan years beginning on or after January 1, 2018, effective on the effective date of this rule. However, there are currently requirements in § 147.104(b)(1)(i)(C) that, by cross-referencing § 155.725, apply those same requirements marketwide, and we did not propose to remove that marketwide requirement. We proposed changes to § 147.104 to reflect the SHOP changes. Specifically, we proposed to eliminate, from § 147.104(b)(1)(i)(C), the cross-reference to § 155.725. We proposed in place of the cross-reference to explicitly specify in § 147.104(b)(1)(i)(C) those same coverage effective dates for coverage in the small group market, and for the large group market if such coverage is offered through a SHOP, that would be eliminated from the SHOP regulations under our proposal for § 155.725. We are finalizing this proposal, but are modifying the language that will replace the cross-reference to clarify that it is permissible for issuers to apply an effective date of coverage that is *before* or on the specified dates. We are also modifying the proposed language so that the effective date of coverage is tied to the date a group enrollment is received, rather than to the date a plan selection is received.

Comment: All commenters supported in principle the proposal to eliminate, from § 147.104(b)(1)(i)(C), the cross reference to the effective dates of coverage in § 155.725, and in its place explicitly specify in § 147.104(b)(1)(i)(C) those effective dates for coverage in the small group market, and for the large group market if such coverage is offered through a SHOP. However, several commenters noted that our proposal did not import the provisions in § 155.725, describing the coverage effective dates, verbatim into § 147.104(b)(1)(i)(C). They observed that the proposed language in § 147.104(b)(1)(i)(C) tied the coverage effective date to the date a plan selection was received, rather than to the date a group enrollment was received, and that tying the coverage date to the date a group enrollment was received (as in the effective-date-of-coverage language currently set forth in § 155.725) would be more appropriate. Commenters also stated that the language we proposed to add in § 147.104(b)(1)(i)(C), unlike the language in current regulations in § 155.725, would prohibit issuers from applying a coverage effective date that falls *before* the first day of the following month, or *before* the first day of the second following month, as applicable, after the date a group enrollment is received.

Response: As commenters pointed out, in the language we proposed for § 147.104(b)(1)(i)(C), we tied the coverage effective date to the date a plan selection, rather than a group enrollment, was received. Given that the proposed language we added appears in a section of the rules (§ 147.104) that applies marketwide, and not just in SHOPs, we agree with the commenters that tying the coverage date to a group enrollment, which is a broader term than a plan selection (the latter is a SHOP-specific term), would be more appropriate. We also agree with the commenters that the existing language in § 155.725, which requires issuers to ensure a coverage effective date *of,* rather than *on,* the dates specified in the existing language, permits issuers to apply an enrollment date that falls *before,* rather than only *on,* the first day of the first month or the first day of the second month (as applicable) following the date a group enrollment is received, and that issuers should continue to have

the flexibility to apply an enrollment date that falls *before* those dates. Therefore, in light of those comments, we are finalizing language in § 147.104(b)(1)(i)(C).

ii. Special Enrollment Periods

Section 147.104(b)(2)(i) extends several of the special enrollment periods that apply to issuers on the Exchange, to all issuers in the individual market. Although § 147.104(b)(2)(i) is intended to specify which special enrollment periods offered through the Exchange must also be offered by health insurance issuers with respect to coverage offered outside of an Exchange, the paragraph as currently written could be read to apply the exceptions to any coverage offered by a health insurance issuer in the individual market. We recognize the potential for confusion, as coverage offered through an Exchange is offered by a health insurance issuer in the individual market, but this coverage is subject to the special enrollment rule at § 155.420(d), which is intended to require special enrollment periods for qualifying events including those listed in the exceptions in § 147.104(b)(2)(i). Therefore, we proposed to amend that phrase in § 147.104(b)(2)(i) to clarify that the exceptions in the paragraph only apply with respect to coverage offered outside of the Exchange in the individual market. We received no comments on this proposal, and are finalizing it as proposed.

With respect to the subset of special enrollment periods in § 155.420 that apply off-Exchange, current regulations at § 147.104(b)(2)(ii) state that, in applying § 147.104(b)(2), 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. As discussed in the preamble to § 155.420, we are finalizing a change to § 155.420(a)(5) to exempt qualified individuals from the prior coverage requirement that applies to certain special enrollment periods if they lived in a service area where no qualified health plan was available through the Exchange for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420. Section 155.420(a)(5) applies to qualifying individuals seeking off-Exchange coverage through an applicable special enrollment period, so we proposed that this exception for individuals living in a service area where there were no QHPs offered through an Exchange would also apply.[9] However, in this instance the reference to ''QHP'' should not be deemed to refer to a plan for purposes of applying § 147.104(b)(2). Therefore, we proposed to amend § 147.104(b)(2)(ii) to state that a reference in § 155.420 (other than in § 155.420(a)(5)) 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. We are finalizing this change as proposed.

Comment: All commenters supported this proposal, while some commenters stated more generally that special enrollment periods should be the same, regardless of whether an individual is seeking coverage on or off-Exchange. One commenter suggested that we publish a list of bare counties so that the exemption to the prior-coverage requirement can be properly applied both on and off-Exchange.

Response: We are finalizing the proposal, consistent with the way in which the amendment to § 155.420(a)(5) is being finalized, and if there are ever any service areas in which no qualified health plans are offered through the Exchange, we will consider publishing a list of them, as the commenter suggested. For a more detailed response to comments regarding the amendment to § 155.420(a)(5), see the preamble to that section.

Among the special enrollment periods in § 155.420 that apply off-Exchange are those specified in § 155.420(d)(2)(i), under which a qualified individual gains a dependent or becomes a new dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order. We sought comment on whether this special enrollment period should afford an individual's existing dependents an independent opportunity to enroll, off-Exchange, in new coverage or make changes to their existing coverage. As applied to on-Exchange coverage, when a qualified individual gains or becomes a new dependent under the circumstances described in § 155.420(d)(2)(i), the qualified individual is afforded a special enrollment period to enroll in or change Exchange coverage with his or her dependents, including his or her newly-gained dependent, in accordance with any applicable metal level restrictions outlined in § 155.420(a)(4)(i). The new dependent is also afforded an independent special enrollment period under which he or she can enroll in or change Exchange coverage as a subscriber, as opposed to as a dependent of the qualified individual. Under the HIPAA special enrollment provisions that continue to apply to group health plans and health insurance issuers in connection with group health coverage, there are similar special enrollment periods when a child becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.[10] We sought comment on whether, in the off-Exchange individual market, the special enrollment periods for when an individual gains a dependent or becomes a new dependent under the circumstances described in § 147.104(b)(2), which cross-references § 155.420(d)(2)(i), should continue to operate in the same manner as they do on-Exchange, whether they should operate in a manner consistent with the HIPAA group market regulations, or whether we should adopt some other approach.

With respect to off-Exchange coverage, we are maintaining current policy under which an individual who qualifies for a special enrollment period for gaining a dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order under § 147.104(b)(2) may enroll in or change coverage along with his or her dependents, including the newly-gained dependent(s) and any existing dependents. The new dependent is also afforded an independent special enrollment period under which he or she can enroll in or change coverage as a subscriber, as opposed to as a dependent of the

[9] As stated in the preamble in the proposed rule to § 155.420, the exception to the requirement to have previous coverage is intended to relieve individuals of that requirement when there was no *affordable* coverage (that is, coverage that could be purchased through an Exchange to which APTC might apply) available in their previous service area. We believe affordability is key to this exception, and therefore, that the scope of the exception should apply equally, regardless of whether the individual is seeking to purchase coverage inside *or* outside an Exchange during the special enrollment periods for which this exception applies; that is, the exception should apply if there was no such affordable coverage available in the individual's previous service area (regardless of whether or not any coverage was being actively marketed in that service area outside the Exchange). Also, when an individual sought to purchase coverage outside an Exchange during such a special enrollment period, we believe it might be unreasonably difficult for an issuer to determine if at least one issuer was actively marketing coverage in the individual's previous service area outside the Exchange, as opposed to determining if at least one issuer was making coverage available in that service area specifically through an Exchange. We solicited comments on this approach.

[10] See § 146.117(b).

individual. This off-Exchange special enrollment period does not otherwise provide to existing dependents an independent opportunity to enroll in new coverage or make changes to their existing coverage.

Comment: Some commenters stated that existing dependents should be entitled to enroll with other family members who have qualified for the special enrollment period when a qualified individual in their household gains a dependent or becomes a new dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order, while others believed they should not, stating that allowing this practice would contribute to adverse selection. Some commenters stated that special enrollment periods should apply uniformly on-Exchange and off-Exchange.

Response: As stated previously, we are continuing to apply the parameters of the special enrollment period for those who have gained or become a new dependent through marriage, birth, adoption, foster care placement, or a child support or other court order off-Exchange in the same manner as applied on-Exchange. We believe the advantages and simplicity of uniformity between on-Exchange and off-Exchange coverage in this instance outweigh the concern about adverse selection.

iii. Technical Changes

We proposed to remove paragraph § 147.104(b)(1)(iii), along with the cross-reference to it in § 147.104(b)(1)(ii), as paragraph (b)(1)(iii) applies to plan selections made in 2013, and is therefore no longer necessary. We received no comments regarding this proposal, and are finalizing these changes as proposed.

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

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2018,[11] both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2018 sequestration. The Federal government's 2018 fiscal year began October 1, 2017. Although the 2016 benefit year was the final year of the transitional reinsurance program, HHS will continue to make reinsurance payments in the 2018 fiscal year, as the second contribution collection deadline for the 2016 benefit year was November 15, 2017. Therefore, the reinsurance program will be sequestered at a rate of 6.6 percent for payments made from fiscal year 2018 resources (that is, funds collected during the 2018 fiscal year). The risk adjustment program will also be sequestered at a rate of 6.6 percent for payments made from fiscal year 2018 resources (that is, funds collected during the 2018 fiscal year).

HHS, in coordination with the 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 the reinsurance and risk adjustment programs, the funds that are sequestered in fiscal year 2018 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2019 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.

2. Provisions and Parameters for the Risk Adjustment Program

In subparts D and G of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the PPACA 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. Beginning with the 2017 benefit year, HHS is operating risk adjustment in every State, and did not receive any applications from States to operate risk adjustment for the 2019 benefit year.

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

The HHS risk adjustment model predicts plan liability for an average enrollee based on that person's age, sex, and diagnoses (risk factors), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each of these age groups. In each of the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, in the adult models, we added enrollment duration factors beginning for the 2017 benefit year, and prescription drug utilization factors (RXCs) beginning for the 2018 benefit year, in the calculation of enrollees' risk scores. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of 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.

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

For the 2019 benefit year, we proposed to recalibrate the risk adjustment models using the methodology finalized for the 2018 benefit year, with small modifications to the drug classes included in the 2019 benefit year adult models, and incorporation of the 2016 benefit year enrollee-level EDGE data in the 2019 benefit year risk adjustment model recalibration.

i. Recalibration Using EDGE Data

To recalibrate the 2016, 2017 and 2018 benefit year risk adjustment models, we used the 3 most recent years of Truven MarketScan® data. This approach 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 rare conditions with small sample sizes. We finalized in the 2018 Payment Notice the collection of enrollee-level EDGE data and the recalibration of the risk adjustment model for the 2019 benefit year using 2016 benefit year EDGE data. We believe that blending the coefficients calculated from the 2016 benefit year enrollee-level EDGE data with MarketScan® data will provide stability within the risk

[11] Available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/sequestration_reports/2018_jc_sequestration_report_may2017_potus.pdf.*

adjustment program and minimize volatility in changes to risk scores from the 2018 to 2019 benefit years due to differences in the datasets' underlying populations. As such, we proposed blending 3 years of data to recalibrate the coefficients used in the risk adjustment models and, for the 2019 benefit year, blending separately solved coefficients from the 2016 benefit year enrollee-level EDGE data and the 2014 and 2015 MarketScan® data.

Given the timing of the proposed rule, we were not able to incorporate the 2016 benefit year enrollee-level EDGE data in the proposed rule. Instead, we used the 2014 and 2015 MarketScan® data for the coefficients displayed in the proposed rule. We proposed to finalize the 2019 benefit year blended coefficients with the separately solved models from the 2016 benefit year enrollee-level EDGE data, and the 2014 and 2015 MarketScan® data. This is similar to our approach in previous years, in which we updated the final coefficients using data from the most recently available benefit year.[12] We explained that we expected to publish the final risk adjustment model coefficients for the 2019 benefit year in the final rule. However, we sought comment on whether we should publish the final risk adjustment model coefficients in guidance in the spring of 2018, prior to rate setting for the 2019 benefit year, if we needed additional time to analyze the 2016 enrollee-level EDGE data. Under either approach, we proposed that the final risk adjustment model coefficients for the 2019 benefit year would be determined using the methodology that we would finalize in this rule, and would be published prior to the 2019 benefit year rate setting. Additionally, if we found significant demographic or distributional differences in the enrollee-level EDGE data compared to the MarketScan® data, we sought comment on whether we should make adjustments to the risk adjustment recalibration model age-sex, hierarchical condition categories (HCCs), and RXC categories for the 2019 benefit year. In such a case, we proposed we would make adjustments to the models to better align them with the enrollee-level EDGE data, to improve the prediction of plan liability.

We sought comment on our proposal to determine coefficients based on a blend of 2014 and 2015 MarketScan® data and 2016 enrollee-level EDGE data. We also sought comment on the proposed methodology to equally weight the separately solved model coefficients from the 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data for the final coefficients, instead of using only the 2016 enrollee-level EDGE data to recalibrate the risk adjustment model coefficients for the 2019 benefit year.

We are finalizing the approach using equally blended coefficients from separately solved 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data to recalibrate the risk adjustment model coefficients for the 2019 benefit year. We are not making any changes to age-sex or HCC categories, because we did not find significant distributional differences, and we will continue to assess whether to propose any specific changes to the categories for future benefit years in future rulemaking. We did not propose and are not making any changes to the enrollment duration categories. Please see the preamble section below on ''Prescription Drugs'' for a discussion of changes being finalized with respect to the RXC categories. The final risk adjustment model coefficients for the 2019 benefit year risk adjustment program are listed in Tables 2, 4 and 5 of this rule.

Comment: Commenters supported the use of enrollee-level EDGE data in model recalibration noting the data would more closely reflect the relative risk differences of individuals in the individual and small group markets compared to the MarketScan® data. Most commenters also supported equally blending coefficients from separately solved models using 3 years of data to promote stability year over year, thereby phasing in the use of enrollee-level EDGE data. A few commenters supported overweighting the 2016 enrollee-level EDGE data, with one commenter supporting overweighting of the 2016 data if sample sizes are adequate. A few commenters supported using only the 2016 enrollee-level EDGE data for recalibration, stating that MarketScan® data will have different utilization and risk patterns, and socioeconomic status for enrollees with employer-based coverage than the EDGE data, which directly reflects PPACA individual and small group market enrollees. These commenters also stated that these differences in the underlying data could cause the risk adjustment coefficients to over- or under-predict risk differences. One commenter stated that relying on older data to calibrate the model could lead to significant gaps in the risk adjustment methodology. One commenter requested clarification as to the volatility in changes to risk scores from the 2018 to 2019 benefit years that could occur due to differences in the datasets' underlying populations. Another commenter requested that recalibration using EDGE data be postponed until all States' data is available in the 2017 benefit year.[13] Some commenters requested separate publication of the coefficients from the 2016 enrollee-level EDGE data. One commenter requested clarification as to what weights would be applied in blending coefficients from the 3 years of data. Most commenters also supported HHS finalizing the 2019 benefit year coefficients prior to rate setting in guidance, while a few others requested the coefficients be finalized in the final rule. One commenter noted that delaying publication of the final coefficients past the publication of the final rule would pose challenges in issuers' rate setting timelines, while some commenters suggested that if HHS needs additional time beyond the publication of the final rule, the final coefficients for the 2019 benefit year should be published no later than February 28, 2018.

Response: For small sample sizes, year-to-year differences in spending due to data anomalies can cause significant differences in a particular solved coefficient. We agree that blending coefficients from multiple years of data can provide stability in changes in the recalibrated model coefficients and provide certainty to issuers, particularly where small sample sizes could lead to volatility in the solved coefficients from year-to-year. Additionally, while there are differences in total spending in MarketScan® compared to enrollee-level EDGE data, we have found that the relative risk differences for age-sex, HCC and RXC categories are generally similar to those in the MarketScan® data, and therefore, do not believe that blending the data will cause significant over- or under-prediction of relative risk scores on average. Enrollee-level EDGE data shows lower spending and relative risk patterns for shorter enrollment durations compared to the MarketScan® data, resulting in smaller enrollment duration coefficients for all 11 months. This result was expected, given that enrollees in large group coverage have longer enrollment duration and a higher proportion of individuals with a full-year of enrollment on average than enrollees in the individual and small group markets, and that the greater number of shorter average enrollment durations in the enrollee-level EDGE

[12] See, for example, 2018 Payment Notice, 81 FR 94058 (December 22, 2016).

[13] Massachusetts is not included in the 2016 benefit year enrollee-level EDGE data, because Massachusetts operated its own risk adjustment program through the 2016 benefit year.

data account for lower relative risk on average.

Additionally, while Massachusetts is not included in the 2016 benefit year enrollee-level EDGE data, the relative risk differences for enrollees in Massachusetts are likely similar on average to those for enrollees in other States. The 2017 benefit year enrollee-level risk EDGE data will not be available until the end of summer 2018, after the 2019 benefit year risk adjustment factors need to be published to support 2019 benefit year benefit design and rate development, and therefore cannot be used for this recalibration effort. We believe that a national dataset of individual and small group market claims experience for the most recent benefit year is the preferable data source—even without the incorporation of one State—compared to only using commercial claims data for risk adjustment model recalibration and risk estimation in the individual and small group markets.

In all, we believe blending the coefficients promotes stability and certainty for issuers in rate setting, smoothing any significant differences as with the EDGE enrollment duration factors, while maintaining the relative average risk differences stakeholders have expected from the MarketScan®-only coefficients. Therefore, we are finalizing our proposal to equally weight coefficients from separately solved models using 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data for the final 2019 benefit year risk adjustment model recalibration. We also were able to complete our analysis of the 2016 EDGE data in time to publish the final coefficients blended with 2016 enrollee-level EDGE data in this final rule. The final 2019 benefit year risk adjustment model coefficients listed in Tables 2, 4, and 5 are blended coefficients using equally weighted coefficients solved from the 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data.

Comment: Commenters requested clarification on the analytical dataset development process using the 2016 enrollee-level EDGE data, sample size of the enrollee-level EDGE data, and differences in EDGE and MarketScan® data.

Response: We arrived at the 2016 enrollee-level EDGE analytical dataset using several criteria. We limited the sample to ages 0–64 to maintain the same age categories as those HHS has used in the MarketScan® data, with which the EDGE coefficients are blended. Currently, we use the age 60–64 factors for those over 65 years of age enrolled in individual and small group market coverage, and will continue to do so for the 2019 benefit year. We will consider whether to propose expanding the age and sex factors to include age groups and associated costs for enrollees ages 65 and above in future model recalibrations. We also excluded derived claims, any newborn diagnoses for infants older than one year of age, anomalous claims (for example, pregnancy diagnoses if sex is male) and those with sex unknown. There were approximately 47 million, 28 million and 31 million total unique enrollees in the 2014 MarketScan®, 2015 MarketScan®, and 2016 enrollee-level EDGE data, respectively. Relative risks were similar in the 2016 enrollee-level EDGE data for most categories in all three adult, infant and child samples. As mentioned above, enrollee-level EDGE data reflected lower spending and relative risk patterns for shorter enrollment duration enrollees compared to MarketScan® data.

Comment: In case of significant demographic or distributional differences in the EDGE data compared to the MarketScan® data, most commenters supported HHS making adjustments to give greater weight to the EDGE data when recalibrating the model coefficients. However, commenters did not support making changes to the age-sex, HCC, enrollment duration or RXC factors categorizations beyond what was in the proposed rule, and instead supported such changes to be implemented for the 2020 benefit year.

Response: We did not identify significant differences in the relative risk for enrollees over 65 compared to those in the 60–64 age group in the enrollee-level EDGE data compared to the MarketScan® data, and therefore, are finalizing the risk adjustment model categories as proposed. As noted above, we will continue to assess relative differences in demographic and spending patterns in the EDGE data and will consider amending the risk adjustment model categories in future recalibrations, particularly once we have multiple years of enrollee-level EDGE data.

Comment: A few commenters requested that HHS limit the scope of enrollee-level EDGE data collection and use, clarify the types of data elements collected in the enrollee-level EDGE data, proceed with caution given the data privacy and trade secret information, and prohibit any other use of the data.

Response: These comments are outside the scope of the proposed rule. As finalized in the 2018 Payment Notice, HHS is collecting enrollee-level EDGE data, which provides more granular claims data from the individual and small group markets, and is being used to improve the recalibration of HHS programs. Additionally, as noted in the 2018 Payment Notice, HHS recognizes the sensitivity of enrollee-level EDGE data, and is not collecting masked enrollee IDs from issuers' EDGE servers, plan or issuer IDs, rating areas, or State data elements to safeguard the privacy and security of protected health information (PHI) and minimize potential risks to issuers' proprietary information.

ii. Prescription Drugs

In the 2018 Payment Notice, we finalized the inclusion of 12 RXCs that interact with HCCs, or drug-diagnosis (RXC–HCC) pairs, in the adult risk adjustment models for the 2018 benefit year. Ten of the RXC–HCC pairs have three levels of incremental predicted costs (diagnosis-only, prescription drug-only, and both diagnosis and prescription drug), indicating that they can be used to impute a particular diagnosis. The 2018 benefit year risk adjustment adult models also included two RXC–HCC pairs that are used for severity-only—that is, they predict incremental costs for enrollees with the diagnosis-only, or with both the diagnosis and the prescription drug. For enrollees without the associated diagnoses documented for these severity-only RXC–HCC pairs, the presence of the drug alone would not lead to the attribution of additional plan liability costs to the plan.

For the 2019 benefit year, we proposed to remove the two severity-only RXCs (RXC 11: Ammonia Detoxicants, and RXC 12: Diuretics, Loop and Select Potassium-Sparing). Both have low average costs per enrollee per year and were constrained in the 2018 benefit year adult risk adjustment models final coefficients to the average cost of the drugs to avoid overcompensating issuers for these RXCs. Constraining these RXCs removed overprescribing and gaming incentives to prescribe a low-cost drug to receive a much larger risk adjustment payment. However, after constraints, these two severity-only RXCs have extremely small coefficients that no longer predict meaningful incremental plan risk associated with a severe health condition. Therefore, we proposed eliminating these two RXCs from the adult models beginning with the 2019 benefit year. As explained in the proposed rule, we believe the remaining RXCs do not engender significant gaming concerns due to the cost and side-effects of the drugs if prescribed

without cause. As we noted in the 2018 Payment Notice, where the risk of unintended effects on provider prescribing behavior is low, we will continue to include a small number of prescription drug classes as predictors of risk and plan liability. For the remaining RXCs, we explained there is a high rate of presence of a diagnosis code in the associated HCC in the MarketScan® data, indicating a positive predictive value for using these RXCs to impute missing diagnoses. Additionally, we noted that we intend to monitor prescription drug utilization for unintended effects, and may propose to remove drug classes based on such evidence in future rulemaking. We are finalizing the removal of RXC11 and RXC12 from the adult risk adjustment models beginning with the 2019 benefit year. Table 1 contains the final list of prescription drug factors included in the 2019 benefit year risk adjustment adult models. We will continue to evaluate the effects of incorporating prescription drugs in the adult models to determine whether to continue, broaden or reduce the impact of this set of factors.

Comment: Most commenters supported the removal of the two severity-only RXCs due to their low impact in predicting meaningful differences in risk. Commenters also supported HHS's intention to evaluate the impact of incorporating the prescription drug factors in the model and adding or removing drugs in future model recalibrations as appropriate. Commenters generally supported the inclusion of prescription drug factors in the HHS risk adjustment model, noting the benefit in imputing missing diagnoses. Additionally, we note that commenters on the Request for Information also supported the inclusion of prescription drugs in the risk adjustment methodology. One commenter to the proposed rule suggested HHS should use the MedID for drug classification instead of the RXNorm Concept Unique Identifier (RXCUI) system. The commenter noted MedID would improve stability, accessibility and predictability of the RXCs, as acquiring RXCUI mapping, keeping it up to-date, anticipating changes and ensuring drug inclusion has been a challenge for issuers in determining formularies and often excludes some drugs. Another commenter sought clarification as to whether drugs administered through hospital, office-based or home health settings and found on medical claims would receive credit for the RXC factors, in addition to drugs found on pharmacy claims. One commenter requested HHS release a mapping of RXCUIs to RXC factors for issuers to adequately assess how inclusion and exclusion of drugs will impact risk adjustment, and suggested HHS provide a crosswalk with the RXCUIs mapped to the RXCs prior to January 1, 2018. The commenter also noted that since there is a lag in the data used for recalibration, HHS should consider how to incorporate newer drugs that are approved after the data years and before or during the benefit year. On the other hand, commenters who had a chance to review the draft RXC crosswalk HHS released in September 2017 for the 2018 benefit year risk adjustment adult models suggested that if a drug is included, then all strengths and formulations of that drug ought to be included in the drug class, including the generic or brand name drugs, or requested clarification as to why specific drugs were excluded. A few commenters requested that HHS consider including prescription drugs used by individuals with mental health and substance use disorders in the model, with one suggesting that adding drugs used by those with mental health and substance use disorders to the model may better capture the costs associated with these individuals, and citing a study suggesting that those costs may not be well captured in the associated HCCs in the current model.[14]

Response: We are finalizing our proposal to remove the two severity-only RXCs (RXC 11: Ammonia Detoxicants, and RXC 12: Diuretics, Loop and Select Potassium-Sparing) from the 2019 benefit year risk adjustment adult models. As we explained in the 2018 Payment Notice, we selected the RxNorm tool developed by the U.S. National Library of Medicine because it is frequently updated, reliable, and easily accessible, and issuers commented on the ease of the RxNorm tool in mapping drugs to RXCUIs. As such, we do not see a need to adopt another classification system at this time. HHS posted an RXC to RXCUI draft crosswalk on September 18, 2017,[15] to provide issuers an initial set of RXCUIs that would be included for 2018 benefit year risk adjustment adult models in the HHS-operated risk adjustment program. As we noted in the crosswalk, drugs were excluded based on expert or clinician input as to drugs' cross indications, empirical and statistical analyses that indicated a weak association between the drug and the diagnoses, or if drugs were older or discontinued. Drugs were also excluded in situations where drugs had substantially lower costs compared to other drugs included in the RXC, and therefore these drugs were less likely to be the focus of risk-selection behavior by health plans. In these instances, USP classes contained a mix of newer, more expensive drug treatments, and older, often generic, lower-cost drug treatments. For example, the combined USP classes Immune Suppressants and Immunomodulators encompass a wide range of drugs. They include expensive biologics costing several thousands of dollars each month and drugs like generic methotrexate, a month's supply of which can cost less than $100. Clinician review determined that many of the drugs in this class are substitutable and the general prescribing process would be to first prescribe a cheaper drug, and if the patient does not respond to that then move to a more expensive biologic. However, because concern over patient access and health plan selection behavior (reflected in formulary design) centers around the expensive biologics, the cheaper non-biologics were removed from RXC 9.

We review drugs in the United States Pharmacopeia (USP) classification and consult clinicians and experts to ensure relevant drugs are included. However, as some commenters noted in response to the proposed rule, new drugs have been released since we released the draft 2018 benefit year crosswalk and a few drugs that may be eligible under our other criteria were not classified by the USP classification version used for the draft crosswalk. We expect to publish the final 2018 benefit year crosswalk in the spring of 2019, after the conclusion of the 2018 benefit year, so that newly approved drugs released through the end of the year and the latest USP classification are evaluated and included, as appropriate. As such, we intend to make quarterly updates to the 2018 benefit year prescription drug crosswalk, to ensure we are capturing all new drug releases and drug class inclusions or modifications. We are also reviewing drugs administered through clinicians in hospital, office-based, or

[14] Montz, E., Layton, T., Busch, A.B., Ellis, R.P., Rose, S., & McGuire, T.G. (2016). Risk-adjustment simulation: Plans may have incentives to distort mental health and substance use coverage. Health Affairs, 35(6), 1022–1028.

[15] Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk Memorandum. September 18, 2017. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf.*

2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXCs) Crosswalk. September 18, 2017. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RARx_RxCUIs-Crosswalk-9-6-17.xlsx.*

home health settings crosswalked to national drug codes (NDCs) to determine whether it is appropriate under our inclusion criteria to include these drugs in the 2018 benefit year crosswalk for 2018 benefit year risk adjustment risk score calculation. However, as these drugs are often more expensive when administered in hospital, office-based, or home health settings, we are not including such drugs in the recalibration of the adult models for the 2019 benefit year to limit gaming incentives. We anticipate the 2019 benefit year drug crosswalk will be published on a similar quarterly schedule, following the final 2018 benefit year crosswalk publication. We also intend to monitor the impact of the drugs included in the adult models on prescribing incentives and will evaluate adding or removing other RXCs as appropriate in future recalibrations for future benefit years. We had previously considered, but did not include, antimanic agents for depression and bipolar disorders due to their low imputation value in identifying the risk solely based on the RXC and low relative cost of the drugs. We are continuing to assess if mental health and substance use disorder treatments should be included in the adult models in future benefit years.

Comment: One commenter noted that pharmacy claims should not be included in the risk adjustment data validation process as no clinical documentation is available for pharmacy claims, and HHS should not include data that cannot be easily audited in risk adjustment. Another commenter sought clarification as to how HHS intends to conduct risk adjustment data validation for prescription drugs included in the risk adjustment adult models.

Response: As we noted in the 2018 Payment Notice, HHS does not perform risk adjustment data validation audits with the intent of determining whether a clinician correctly diagnosed a patient. Rather, the goal for the HHS-operated risk adjustment program is to ensure 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 and beyond. We will consider whether additional adjustments to the risk adjustment data validation process are needed for the 2018 benefit year to ensure risk adjustment data validation appropriately audits pharmacy claims submitted to EDGE by issuers.

TABLE 1—FINAL DRUG-DIAGNOSIS (RXC–HCC) PAIRS FOR THE 2019 ADULT MODEL

RXC	RXC label	HCC	HCC label	Final RXC use
RXC 01	Anti-HIV Agents	001	HIV/AIDS	imputation/severity.
RXC 02	Anti-Hepatitis C (HCV) Agents.	037C, 036, 035, 034	Chronic Hepatitis C, Cirrhosis of Liver, End-Stage Liver Disease, and Liver Transplant Status/Complications.	imputation/severity.
RXC 03	Antiarrhythmics	142	Specified Heart Arrhythmias	imputation/severity.
RXC 04	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.
RXC 05	Inflammatory Bowel Disease Agents.	048, 041	Inflammatory Bowel Disease, Intestine Transplant Status/Complications.	imputation/severity.
RXC 06	Insulin	019, 020, 021, 018	Diabetes with Acute Complications; Diabetes with Chronic Complications; Diabetes without Complication, Pancreas Transplant Status/Complications.	imputation/severity.
RXC 07	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.
RXC 08	Multiple Sclerosis Agents	118	Multiple Sclerosis	imputation/severity.
RXC 09	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.
RXC 10	Cystic Fibrosis Agents	159, 158	Cystic Fibrosis, Lung Transplant Status/Complications.	imputation/severity.

iii. High-Cost Risk Pool Adjustment

HHS finalized a high-cost risk pool adjustment in the 2018 Payment Notice to account for the incorporation of risk associated with high-cost enrollees in the risk adjustment model. Specifically, we finalized adjusting the risk adjustment model for high-cost enrollees beginning for the 2018 benefit year by excluding a percentage of costs above a certain threshold level in the calculation of enrollee-level plan liability risk scores so that risk adjustment factors are calculated without the high-cost risk, because the average risk associated with HCCs and RXCs is better accounted for without the inclusion of the high-cost enrollees. In addition, to account for issuers' risk associated with the high-cost enrollees, issuers will be compensated for a percentage of costs above the threshold. We set the threshold and percentage of costs at a level that would continue to incentivize issuers to control costs while improving the risk prediction of the risk adjustment model. Issuers with high-cost enrollees will receive a payment for the percentage of costs above the threshold in their respective transfers. Using claims data submitted to the EDGE server by issuers of risk adjustment covered plans, HHS will calculate the total amount of paid claims costs for high-cost enrollees based on the threshold and the coinsurance rate. HHS will then calculate a charge as a percentage of the issuers' total premiums in the individual (including catastrophic and non-catastrophic plans and merged

market plans), or small group markets, which will be applied to the total transfer amount in that market, maintaining the balance of payments and charges within the risk adjustment program. In the 2018 Payment Notice, we finalized a threshold of $1 million and a coinsurance rate of 60 percent across all States for the individual (including catastrophic and non-catastrophic plans and merged market plans) and small group markets for the 2018 benefit year.

For the 2019 benefit year, we proposed to maintain the same parameters that apply to the 2018 benefit year. Therefore, we proposed to maintain a $1 million threshold and 60 percent coinsurance rate for the high-cost risk pool for the 2019 benefit year risk adjustment program. We explained that we believe this threshold and coinsurance rate would result in total payments or charges nationally that are very small as a percentage of premiums for issuers, and will prevent States and issuers with very high-cost enrollees from bearing a disproportionate amount of unpredictable risk. We sought comments on alternative methods for reimbursing issuers for exceptionally high-cost enrollees through the high-cost risk pool and improving the calculation of plan liability in the HHS-operated risk adjustment models for future benefit years. We also shared suggestions from stakeholders that the pool be multi-tiered, with multiple thresholds and increased coinsurance as the thresholds increase to account for the reduced number of enrollees at higher thresholds where costs to an issuer are catastrophic.

We are finalizing the high-cost risk pool adjustment parameters for the 2019 benefit year as proposed.

Comment: Most commenters supported our proposal to maintain the same high-cost risk pool adjustment parameters as those used for the 2018 benefit year and noted that keeping the parameters the same provides stability and certainty in the markets. One commenter questioned why the parameters are not trended for increasing medical costs. Some commenters noted that the $1 million threshold level may be too high to have any meaningful impact on premiums or provide stability in smaller State markets with low claims costs that would have additional charges assessed, which could cause volatility. A few commenters did not support the high-cost risk pool adjustment to transfers, yet one of these commenters supported the removal of these costs from the risk adjustment model recalibration. One commenter did not support the proposal based on what appears to be a misunderstanding that the high-cost risk pool adjustment requires individuals to pay 40 percent of costs above $1 million. Some commenters did not support tiering the high-cost risk pool adjustment program for the 2019 benefit year without the first year of experience with this adjustment, noting it would lead to additional complexity. One commenter supported a tiered approach in parameters with maximum coinsurance rates of 80 to 90 percent phased in over multiple years, and another commenter supported a tiered approach if the approach and parameters result in an equivalent cost and scope as the $1 million threshold and 60 percent coinsurance rate parameters.

Response: As we noted in the 2018 Payment Notice, removing extremely high costs improves the risk adjustment model's predictive ability. Additionally, the high-cost risk pool adjustment to the transfer formula mitigates issuers' risk selection incentives to avoid high-cost risk enrollees. Because high-cost enrollees are outliers and thus, unpredictable, they have the potential to significantly distort risk in smaller markets. Removing the high-cost risk from the recalibration model and separately adjusting transfers will allow for greater stability in risk scores to compensate issuers for predictable risk and transfers to compensate issuers for unpredictable risk. We will consider whether a tiered approach would improve model prediction and better compensate issuers for high-cost enrollees than the current approach for future benefit years. We are continuing to assess the market impact of tiered approaches nationally on the model's risk prediction and issuers' risk differences, and whether such an approach would meaningfully improve the model in accounting for high-cost enrollees' risk. We continue to believe a $1 million threshold and 60 percent coinsurance rate for the 2019 benefit year are appropriate to incentivize issuers to control costs while improving the risk adjustment model's risk prediction. Additionally, as we noted in the 2018 Payment Notice, if an issuer were to fail the data quality analysis for a risk adjustment transfer and be assessed a default charge under § 153.740(b) on that basis, we would perform additional data quality analysis to determine an issuer's eligibility for high-cost risk pool adjustments.

We are finalizing our proposal to maintain a $1 million threshold and 60 percent coinsurance rate for the high-cost risk pool for the 2019 benefit year risk adjustment program.

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

The final factors resulting from the equally weighted blended factors from the 2014 and 2015 MarketScan® data and the 2016 enrollee-level EDGE data separately solved models (with the incorporation of the partial year enrollment adjustment and prescription drugs reflected in the adult models only) are shown in Tables 2, 4, and 5. The adult, child and infant models have been truncated to account for the high-cost enrollee pool payment parameters by removing 60 percent of costs above the $1 million threshold as finalized in this rule. As discussed in the preceding section, we are finalizing our proposal to keep the 2019 benefit year high-cost enrollee risk pool payment parameters the same as those finalized for the 2018 benefit year. The final factors for the adult models also reflect the removal of the two severity-only RXCs (RXC 11: Ammonia Detoxicants, and RXC 12: Diuretics, Loop and Select Potassium-Sparing) discussed above in the preamble section on ''Prescription Drugs.'' Table 2 contains factors for each adult model, including the age-sex, HCCs, RXCs, HCC–RXC interaction, and enrollment duration coefficients. As we previously noted,[16] 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.

Table 3 contains the HHS HCCs in the severity illness indicator variable. Table 4 contains the factors for each child model. Table 5 contains the factors for each infant model. Tables 6 and 7 contain the HCCs included in the infant model maturity and severity categories, respectively.

Comment: A few commenters requested for HHS to separately publish the coefficients solved only from the 2016 enrollee-level EDGE data.

Response: We are not separately publishing the coefficients from only 1 year of data to avoid any confusion that could be caused from publishing two sets of coefficients in the final rule. However, we note that stakeholders interested in coefficients from the 2016 enrollee-level EDGE data will be able to solve for them based on the proposed and finalized coefficients. We published the model coefficients using equally weighted coefficients solved from the

[16] 2018 Benefit Year Final HHS Risk Adjustment Model Coefficients. April 18, 2017. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

2014 and 2015 MarketScan® data in the proposed rule. The coefficients finalized in Tables 2, 4 and 5 include the coefficients solved from the 2016 enrollee-level EDGE data without changing the coefficients solved from the 2014 and 2015 MarketScan® data published in the proposed rule, and equally weighted coefficients solved from the 3 years of data.

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Demographic Factors					
	Age 21–24, Male	0.167	0.133	0.091	0.051	0.048
	Age 25–29, Male	0.153	0.119	0.078	0.037	0.034
	Age 30–34, Male	0.186	0.144	0.093	0.043	0.039
	Age 35–39, Male	0.236	0.185	0.125	0.063	0.058
	Age 40–44, Male	0.292	0.233	0.164	0.093	0.088
	Age 45–49, Male	0.346	0.280	0.202	0.121	0.115
	Age 50–54, Male	0.455	0.378	0.287	0.192	0.184
	Age 55–59, Male	0.511	0.424	0.324	0.217	0.209
	Age 60–64, Male	0.573	0.473	0.359	0.235	0.225
	Age 21–24, Female	0.269	0.218	0.153	0.088	0.083
	Age 25–29, Female	0.304	0.245	0.173	0.098	0.092
	Age 30–34, Female	0.410	0.338	0.253	0.167	0.160
	Age 35–39, Female	0.491	0.410	0.317	0.226	0.219
	Age 40–44, Female	0.545	0.454	0.352	0.249	0.241
	Age 45–49, Female	0.553	0.458	0.350	0.237	0.229
	Age 50–54, Female	0.616	0.516	0.401	0.278	0.268
	Age 55–59, Female	0.601	0.499	0.380	0.252	0.241
	Age 60–64, Female	0.616	0.505	0.379	0.240	0.229
	Diagnosis Factors					
HCC001	HIV/AIDS	0.626	0.529	0.434	0.359	0.352
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	8.000	7.812	7.688	7.731	7.737
HCC003	Central Nervous System Infections, Except Viral Meningitis	5.750	5.666	5.604	5.625	5.626
HCC004	Viral or Unspecified Meningitis	4.396	4.192	4.060	3.989	3.983
HCC006	Opportunistic Infections	6.143	6.060	6.006	5.972	5.968
HCC008	Metastatic Cancer	21.806	21.372	21.040	21.084	21.087
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	12.392	12.068	11.825	11.807	11.804
HCC010	Non-Hodgkin's Lymphomas and Other Cancers and Tumors	5.575	5.356	5.189	5.117	5.110
HCC011	Colorectal, Breast (Age <50), Kidney, and Other Cancers	4.291	4.074	3.905	3.831	3.823
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.640	2.482	2.356	2.283	2.276
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.211	1.084	0.976	0.860	0.849
HCC018	Pancreas Transplant Status/Complications	4.439	4.246	4.114	4.122	4.122
HCC019	Diabetes with Acute Complications	0.603	0.531	0.463	0.389	0.381
HCC020	Diabetes with Chronic Complications	0.603	0.531	0.463	0.389	0.381
HCC021	Diabetes without Complication	0.603	0.531	0.463	0.389	0.381
HCC023	Protein-Calorie Malnutrition	11.438	11.430	11.416	11.494	11.502
HCC026	Mucopolysaccharidosis	2.380	2.280	2.200	2.137	2.132
HCC027	Lipidoses and Glycogenosis	2.380	2.280	2.200	2.137	2.132
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	NA	NA	NA	NA	NA
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.380	2.280	2.200	2.137	2.132
HCC034	Liver Transplant Status/Complications	2.380	2.280	2.200	2.137	2.132
HCC035	End-Stage Liver Disease	10.515	10.418	10.353	10.334	10.331
HCC036	Cirrhosis of Liver	5.696	5.491	5.349	5.341	5.339
HCC037_1	Chronic Viral Hepatitis C	0.707	0.604	0.545	0.509	0.505
HCC037_2	Chronic Hepatitis, Other/Unspecified	0.703	0.584	0.523	0.474	0.469
HCC038	Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.300	4.155	4.055	4.026	4.024
HCC041	Intestine Transplant Status/Complications	28.253	28.206	28.169	28.209	28.209
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	9.718	9.488	9.318	9.328	9.329
HCC045	Intestinal Obstruction	5.510	5.274	5.115	5.104	5.102
HCC046	Chronic Pancreatitis	4.439	4.246	4.114	4.122	4.122
HCC047	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.	2.243	2.085	1.972	1.896	1.888
HCC048	Inflammatory Bowel Disease	2.192	2.011	1.868	1.765	1.755
HCC054	Necrotizing Fasciitis	5.507	5.332	5.200	5.206	5.207
HCC055	Bone/Joint/Muscle Infections/Necrosis	5.507	5.332	5.200	5.206	5.207
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	3.316	3.130	2.980	2.923	2.918
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.993	0.878	0.780	0.666	0.654
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.654	2.477	2.337	2.257	2.249
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.654	2.477	2.337	2.257	2.249
HCC063	Cleft Lip/Cleft Palate	1.417	1.266	1.155	1.071	1.065
HCC066	Hemophilia	53.096	52.795	52.549	52.553	52.553
HCC067	Myelodysplastic Syndromes and Myelofibrosis	12.454	12.326	12.228	12.227	12.227
HCC068	Aplastic Anemia	12.454	12.326	12.228	12.227	12.227
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.864	7.738	7.636	7.604	7.602
HCC070	Sickle Cell Anemia (Hb–SS)	7.864	7.738	7.636	7.604	7.602
HCC071	Thalassemia Major	7.864	7.738	7.636	7.604	7.602
HCC073	Combined and Other Severe Immunodeficiencies	5.198	5.074	4.982	4.979	4.979
HCC074	Disorders of the Immune Mechanism	5.198	5.074	4.982	4.979	4.979
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.657	2.572	2.503	2.464	2.461
HCC081	Drug Psychosis	3.804	3.574	3.401	3.278	3.265

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC082	Drug Dependence	3.804	3.574	3.401	3.278	3.265
HCC087	Schizophrenia	3.057	2.822	2.651	2.559	2.550
HCC088	Major Depressive and Bipolar Disorders	1.624	1.472	1.350	1.231	1.219
HCC089	Reactive and Unspecified Psychosis, Delusional Disorders	1.624	1.472	1.350	1.231	1.219
HCC090	Personality Disorders	1.124	1.010	0.901	0.780	0.769
HCC094	Anorexia/Bulimia Nervosa	2.549	2.397	2.275	2.201	2.194
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	4.019	3.924	3.847	3.789	3.783
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	1.056	0.963	0.880	0.802	0.795
HCC102	Autistic Disorder	1.124	1.010	0.901	0.780	0.769
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	1.124	1.010	0.901	0.780	0.769
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	9.989	9.853	9.752	9.735	9.732
HCC107	Quadriplegia	9.989	9.853	9.752	9.735	9.732
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	7.568	7.420	7.310	7.278	7.274
HCC109	Paraplegia	7.568	7.420	7.310	7.278	7.274
HCC110	Spinal Cord Disorders/Injuries	5.212	5.008	4.857	4.816	4.812
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	1.965	1.764	1.620	1.534	1.524
HCC112	Quadriplegic Cerebral Palsy	0.302	0.192	0.120	0.072	0.071
HCC113	Cerebral Palsy, Except Quadriplegic	0.255	0.176	0.120	0.072	0.071
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	0.355	0.300	0.265	0.241	0.236
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.262	5.137	5.045	5.027	5.025
HCC117	Muscular Dystrophy	2.064	1.922	1.819	1.720	1.708
HCC118	Multiple Sclerosis	8.436	8.144	7.920	7.895	7.892
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	2.064	1.922	1.819	1.720	1.708
HCC120	Seizure Disorders and Convulsions	1.390	1.248	1.138	1.044	1.035
HCC121	Hydrocephalus	5.922	5.814	5.724	5.696	5.694
HCC122	Non-Traumatic Coma, and Brain Compression/Anoxic Damage	8.310	8.176	8.067	8.059	8.058
HCC125	Respirator Dependence/Tracheostomy Status	26.626	26.590	26.555	26.637	26.644
HCC126	Respiratory Arrest	8.048	7.900	7.794	7.864	7.872
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	8.048	7.900	7.794	7.864	7.872
HCC128	Heart Assistive Device/Artificial Heart	28.421	28.219	28.071	28.120	28.125
HCC129	Heart Transplant	28.421	28.219	28.071	28.120	28.125
HCC130	Congestive Heart Failure	2.800	2.705	2.635	2.624	2.623
HCC131	Acute Myocardial Infarction	8.077	7.789	7.577	7.664	7.672
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.820	4.558	4.388	4.378	4.378
HCC135	Heart Infection/Inflammation, Except Rheumatic	5.473	5.356	5.268	5.237	5.235
HCC142	Specified Heart Arrhythmias	2.467	2.335	2.233	2.158	2.150
HCC145	Intracranial Hemorrhage	7.621	7.366	7.186	7.162	7.159
HCC146	Ischemic or Unspecified Stroke	2.164	2.012	1.918	1.896	1.894
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	3.167	2.994	2.869	2.802	2.796
HCC150	Hemiplegia/Hemiparesis	4.517	4.422	4.355	4.402	4.407
HCC151	Monoplegia, Other Paralytic Syndromes	2.734	2.612	2.525	2.486	2.482
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	9.056	8.976	8.915	9.004	9.013
HCC154	Vascular Disease with Complications	6.714	6.556	6.439	6.424	6.422
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	3.352	3.207	3.101	3.044	3.038
HCC158	Lung Transplant Status/Complications	25.564	25.421	25.310	25.384	25.391
HCC159	Cystic Fibrosis	14.108	13.825	13.596	13.601	13.601
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.878	0.776	0.686	0.591	0.582
HCC161	Asthma	0.878	0.776	0.686	0.591	0.582
HCC162	Fibrosis of Lung and Other Lung Disorders	1.869	1.767	1.693	1.639	1.633
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.270	6.223	6.188	6.194	6.195
HCC183	Kidney Transplant Status	7.462	7.260	7.119	7.070	7.064
HCC184	End Stage Renal Disease	29.905	29.678	29.495	29.641	29.654
HCC187	Chronic Kidney Disease, Stage 5	1.319	1.263	1.224	1.233	1.235
HCC188	Chronic Kidney Disease, Stage 4	1.319	1.263	1.224	1.233	1.235
HCC203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism.	1.156	1.011	0.879	0.670	0.648
HCC204	Miscarriage with Complications	1.156	1.011	0.879	0.670	0.648
HCC205	Miscarriage with No or Minor Complications	1.156	1.011	0.879	0.670	0.648
HCC207	Completed Pregnancy With Major Complications	3.329	2.913	2.690	2.416	2.386
HCC208	Completed Pregnancy With Complications	3.329	2.913	2.690	2.416	2.386
HCC209	Completed Pregnancy with No or Minor Complications	3.329	2.913	2.690	2.416	2.386
HCC217	Chronic Ulcer of Skin, Except Pressure	1.988	1.888	1.818	1.798	1.796
HCC226	Hip Fractures and Pathological Vertebral or Humerus Fractures	8.801	8.587	8.428	8.457	8.460
HCC227	Pathological Fractures, Except of Vertebrae, Hip, or Humerus	3.874	3.744	3.644	3.579	3.575
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	24.334	24.334	24.329	24.357	24.360
HCC253	Artificial Openings for Feeding or Elimination	8.284	8.198	8.131	8.164	8.168
HCC254	Amputation Status, Lower Limb/Amputation Complications	3.486	3.371	3.290	3.313	3.316
	Interaction Factors					
SEVERE x HCC006	Severe illness x Opportunistic Infections	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC008	Severe illness x Metastatic Cancer	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC009	Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC010	Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	7.694	7.897	8.035	8.180	8.193

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
SEVERE x HCC115	Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC135	Severe illness x Heart Infection/Inflammation, Except Rheumatic	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC145	Severe illness x Intracranial Hemorrhage	7.694	7.897	8.035	8.180	8.193
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).	7.694	7.897	8.035	8.180	8.193
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).	7.694	7.897	8.035	8.180	8.193
SEVERE x HCC035	Severe illness x End-Stage Liver Disease	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC038	Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC153	Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene.	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC154	Severe illness x Vascular Disease with Complications	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC163	Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	1.449	1.541	1.596	1.722	1.733
SEVERE x HCC253	Severe illness x Artificial Openings for Feeding or Elimination	1.449	1.541	1.596	1.722	1.733
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).	1.449	1.541	1.596	1.722	1.733
	Enrollment Duration Factors					
	1 month of enrollment	0.417	0.365	0.325	0.306	0.305
	2 months of enrollment	0.382	0.333	0.293	0.275	0.273
	3 months of enrollment	0.327	0.282	0.244	0.227	0.225
	4 months of enrollment	0.279	0.240	0.206	0.189	0.188
	5 months of enrollment	0.249	0.216	0.185	0.169	0.168
	6 months of enrollment	0.207	0.181	0.153	0.138	0.137
	7 months of enrollment	0.189	0.165	0.141	0.126	0.125
	8 months of enrollment	0.137	0.120	0.102	0.091	0.091
	9 months of enrollment	0.097	0.085	0.074	0.067	0.067
	10 months of enrollment	0.070	0.065	0.060	0.057	0.057
	11 months of enrollment	0.064	0.060	0.057	0.055	0.055
	Prescription Drug Factors					
RXC 01	Anti-HIV Agents	7.822	7.257	6.830	6.605	6.580
RXC 02	Anti-Hepatitis C (HCV) Agents	39.880	39.337	38.905	39.062	39.075
RXC 03	Antiarrhythmics	0.113	0.113	0.113	0.113	0.113
RXC 04	Phosphate Binders	0.730	0.730	0.730	0.730	0.730
RXC 05	Inflammatory Bowel Disease Agents	2.022	1.842	1.701	1.509	1.487
RXC 06	Insulin	1.498	1.349	1.185	0.993	0.973
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.495	0.430	0.361	0.272	0.264
RXC 08	Multiple Sclerosis Agents	21.141	20.350	19.757	19.731	19.721
RXC 09	Immune Suppressants and Immunomodulators	13.273	12.681	12.240	12.270	12.268
RXC 10	Cystic Fibrosis Agents	13.045	12.712	12.485	12.565	12.574
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 (Anti-HIV Agents) and HCC 001 (HIV/AIDS).	2.459	2.560	2.655	3.010	3.046
RXC 02 x HCC037_1, 036, 035, 034.	Additional effect for enrollees with RXC 02 (Anti-Hepatitis C (HCV) Agents) and (HCC 037_1 (Chronic Viral Hepatitis C) or 036 (Cirrhosis of Liver) or 035 (End-Stage Liver Disease) or 034 (Liver Transplant Status/Complications)).	2.645	2.838	2.974	3.020	3.025
RXC 03 x HCC142	Additional effect for enrollees with RxC 03 (Antiarrhythmics) and HCC 142 (Specified Heart Arrhythmias).	0.000	0.000	0.000	0.000	0.000
RXC 04 x HCC184, 183, 187, 188.	Additional effect for enrollees with RxC 04 (Phosphate Binders) and (HCC 184 (End Stage Renal Disease) or 183 (Kidney Transplant Status) or 187 (Chronic Kidney Disease, Stage 5) or 188 (Chronic Kidney Disease, Severe Stage 4)).	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041	Additional effect for enrollees with RxC 05 (Inflammatory Bowel Disease Agents) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	−1.192	−1.096	−0.997	−0.888	−0.878
RXC 06 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 06 (Insulin) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	0.421	0.395	0.456	0.533	0.538
RXC 07 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 07 (Anti-Diabetic Agents, Except Insulin and Metformin Only) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	−0.202	−0.184	−0.153	−0.153	−0.155
RXC 08 x HCC118	Additional effect for enrollees with RxC 08 (Multiple Sclerosis Agents) and HCC 118 (Multiple Sclerosis).	−5.507	−4.981	−4.597	−4.422	−4.399
RXC 09 x HCC056 or 057 and 048 or 041.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)) and (HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders) or 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders)).	−0.337	−0.352	−0.336	−0.370	−0.375
RXC 09 x HCC056	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders).	−2.862	−2.632	−2.452	−2.323	−2.307
RXC 09 x HCC057	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders).	−0.595	−0.444	−0.322	−0.175	−0.161

TABLE 2—FINAL ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 09 x HCC048, 041	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	1.128	1.392	1.563	1.764	1.788
RXC 10 x HCC159, 158	Additional effect for enrollees with RxC 10 (Cystic Fibrosis Agents) and (HCC 159 (Cystic Fibrosis) or 158 (Lung Transplant Status/Complications)).	29.170	29.398	29.528	29.588	29.594

TABLE 3—HHS HCCS IN THE SEVERITY ILLNESS INDICATOR VARIABLE

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

TABLE 4—FINAL CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.200	0.149	0.092	0.042	0.038
Age 5–9, Male	0.138	0.100	0.055	0.018	0.015
Age 10–14, Male	0.193	0.152	0.100	0.060	0.058
Age 15–20, Male	0.258	0.209	0.151	0.099	0.095
Age 2–4, Female	0.153	0.109	0.062	0.025	0.022
Age 5–9, Female	0.102	0.068	0.031	0.005	0.003
Age 10–14, Female	0.182	0.142	0.095	0.059	0.056
Age 15–20, Female	0.281	0.224	0.155	0.091	0.086
Diagnosis Factors					
HIV/AIDS	5.368	4.942	4.622	4.506	4.493
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	13.803	13.633	13.522	13.529	13.530
Central Nervous System Infections, Except Viral Meningitis	8.179	8.020	7.905	7.913	7.913
Viral or Unspecified Meningitis	3.563	3.358	3.225	3.077	3.063
Opportunistic Infections	16.934	16.887	16.848	16.832	16.829
Metastatic Cancer	32.479	32.270	32.092	32.101	32.102
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	10.021	9.785	9.590	9.509	9.501
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	7.835	7.601	7.411	7.304	7.292
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.051	2.879	2.737	2.618	2.605
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.051	2.879	2.737	2.618	2.605
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.188	1.057	0.943	0.818	0.805
Pancreas Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Diabetes with Acute Complications	2.550	2.234	2.032	1.749	1.721
Diabetes with Chronic Complications	2.550	2.234	2.032	1.749	1.721
Diabetes without Complication	2.550	2.234	2.032	1.749	1.721
Protein-Calorie Malnutrition	12.783	12.694	12.618	12.658	12.661
Mucopolysaccharidosis	7.948	7.723	7.536	7.494	7.489
Lipidoses and Glycogenosis	7.948	7.723	7.536	7.494	7.489
Congenital Metabolic Disorders, Not Elsewhere Classified	7.948	7.723	7.536	7.494	7.489
Amyloidosis, Porphyria, and Other Metabolic Disorders	7.948	7.723	7.536	7.494	7.489
Adrenal, Pituitary, and Other Significant Endocrine Disorders	7.948	7.723	7.536	7.494	7.489
Liver Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
End-Stage Liver Disease	11.834	11.685	11.584	11.580	11.579
Cirrhosis of Liver	5.782	5.646	5.535	5.507	5.507
Chronic Viral Hepatitis C	6.269	6.114	5.983	5.966	5.967
Chronic Hepatitis, Other/Unspecified	1.200	1.086	0.983	0.923	0.920
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.636	11.494	11.390	11.392	11.391

TABLE 4—FINAL CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Intestine Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.572	11.283	11.063	11.060	11.061
Intestinal Obstruction	4.506	4.310	4.154	4.057	4.049
Chronic Pancreatitis	10.521	10.314	10.163	10.167	10.167
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.265	2.148	2.046	1.948	1.938
Inflammatory Bowel Disease	7.055	6.685	6.402	6.291	6.279
Necrotizing Fasciitis	3.907	3.706	3.544	3.468	3.461
Bone/Joint/Muscle Infections/Necrosis	3.907	3.706	3.544	3.468	3.461
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.282	4.052	3.856	3.762	3.754
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.092	0.970	0.854	0.726	0.714
Osteogenesis Imperfecta and Other Osteodystrophies	1.402	1.292	1.193	1.110	1.102
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.402	1.292	1.193	1.110	1.102
Cleft Lip/Cleft Palate	1.435	1.260	1.121	0.992	0.980
Hemophilia	61.183	60.705	60.325	60.299	60.296
Myelodysplastic Syndromes and Myelofibrosis	14.718	14.596	14.505	14.474	14.470
Aplastic Anemia	14.718	14.596	14.505	14.474	14.470
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	6.928	6.714	6.544	6.456	6.448
Sickle Cell Anemia (Hb–SS)	6.928	6.714	6.544	6.456	6.448
Thalassemia Major	6.928	6.714	6.544	6.456	6.448
Combined and Other Severe Immunodeficiencies	5.849	5.705	5.592	5.531	5.526
Disorders of the Immune Mechanism	5.849	5.705	5.592	5.531	5.526
Coagulation Defects and Other Specified Hematological Disorders	4.662	4.542	4.439	4.366	4.359
Drug Psychosis	5.648	5.392	5.211	5.131	5.125
Drug Dependence	5.648	5.392	5.211	5.131	5.125
Schizophrenia	4.819	4.473	4.217	4.086	4.073
Major Depressive and Bipolar Disorders	2.214	2.007	1.833	1.653	1.636
Reactive and Unspecified Psychosis, Delusional Disorders	2.129	1.931	1.762	1.584	1.567
Personality Disorders	0.622	0.517	0.405	0.257	0.243
Anorexia/Bulimia Nervosa	2.657	2.471	2.318	2.238	2.228
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	2.119	1.961	1.850	1.796	1.790
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.785	1.639	1.526	1.435	1.427
Autistic Disorder	2.017	1.836	1.677	1.511	1.495
Pervasive Developmental Disorders, Except Autistic Disorder	0.686	0.592	0.484	0.349	0.338
Traumatic Complete Lesion Cervical Spinal Cord	11.525	11.463	11.427	11.507	11.514
Quadriplegia	11.525	11.463	11.427	11.507	11.514
Traumatic Complete Lesion Dorsal Spinal Cord	9.265	9.094	8.948	8.933	8.928
Paraplegia	9.265	9.094	8.948	8.933	8.928
Spinal Cord Disorders/Injuries	3.678	3.487	3.339	3.247	3.239
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	4.952	4.754	4.592	4.506	4.499
Quadriplegic Cerebral Palsy	2.968	2.768	2.638	2.642	2.642
Cerebral Palsy, Except Quadriplegic	0.496	0.392	0.322	0.263	0.261
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.422	1.303	1.209	1.137	1.130
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.749	9.588	9.461	9.440	9.440
Muscular Dystrophy	2.584	2.410	2.280	2.179	2.168
Multiple Sclerosis	10.447	10.104	9.835	9.801	9.797
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.584	2.410	2.280	2.179	2.168
Seizure Disorders and Convulsions	2.004	1.852	1.714	1.567	1.553
Hydrocephalus	4.256	4.146	4.063	4.044	4.042
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	5.714	5.590	5.487	5.444	5.440
Respirator Dependence/Tracheostomy Status	31.959	31.852	31.774	31.912	31.924
Respiratory Arrest	9.776	9.552	9.401	9.366	9.360
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	9.776	9.552	9.401	9.366	9.360
Heart Assistive Device/Artificial Heart	22.337	22.078	21.875	21.901	21.904
Heart Transplant	22.337	22.078	21.875	21.901	21.904
Congestive Heart Failure	5.773	5.674	5.588	5.545	5.540
Acute Myocardial Infarction	5.179	5.104	5.062	5.048	5.046
Unstable Angina and Other Acute Ischemic Heart Disease	3.842	3.765	3.707	3.676	3.675

TABLE 4—FINAL CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Heart Infection/Inflammation, Except Rheumatic	11.892	11.786	11.703	11.684	11.683
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	4.742	4.584	4.427	4.311	4.301
Major Congenital Heart/Circulatory Disorders	1.345	1.248	1.130	1.012	1.002
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.876	0.787	0.684	0.591	0.584
Specified Heart Arrhythmias	3.734	3.576	3.438	3.360	3.353
Intracranial Hemorrhage	12.674	12.462	12.308	12.302	12.303
Ischemic or Unspecified Stroke	5.445	5.367	5.318	5.328	5.331
Cerebral Aneurysm and Arteriovenous Malformation	3.374	3.188	3.056	2.980	2.972
Hemiplegia/Hemiparesis	4.146	4.041	3.967	3.933	3.927
Monoplegia, Other Paralytic Syndromes	3.501	3.373	3.284	3.255	3.254
Atherosclerosis of the Extremities with Ulceration or Gangrene	11.717	11.481	11.305	11.230	11.223
Vascular Disease with Complications	14.161	14.049	13.958	13.980	13.981
Pulmonary Embolism and Deep Vein Thrombosis	13.582	13.475	13.396	13.432	13.436
Lung Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Cystic Fibrosis	22.337	22.078	21.875	21.901	21.904
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.375	0.310	0.225	0.134	0.126
Asthma	0.375	0.310	0.225	0.134	0.126
Fibrosis of Lung and Other Lung Disorders	3.073	2.971	2.872	2.801	2.795
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	8.178	8.122	8.074	8.105	8.108
Kidney Transplant Status	12.436	12.166	11.969	11.943	11.938
End Stage Renal Disease	36.073	35.963	35.872	35.976	35.985
Chronic Kidney Disease, Stage 5	4.148	4.017	3.909	3.812	3.806
Chronic Kidney Disease, Severe (Stage 4)	4.148	4.017	3.909	3.812	3.806
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.061	0.906	0.761	0.532	0.507
Miscarriage with Complications	1.061	0.906	0.761	0.532	0.507
Miscarriage with No or Minor Complications	1.061	0.906	0.761	0.532	0.507
Completed Pregnancy With Major Complications	2.897	2.512	2.294	1.986	1.950
Completed Pregnancy With Complications	2.897	2.512	2.294	1.986	1.950
Completed Pregnancy with No or Minor Complications	2.897	2.512	2.294	1.986	1.950
Chronic Ulcer of Skin, Except Pressure	2.338	2.247	2.159	2.086	2.079
Hip Fractures and Pathological Vertebral or Humerus Fractures	5.437	5.163	4.942	4.830	4.822
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.665	1.535	1.404	1.262	1.248
Stem Cell, Including Bone Marrow, Transplant Status/Complications	22.337	22.078	21.875	21.901	21.904
Artificial Openings for Feeding or Elimination	11.371	11.258	11.185	11.294	11.305
Amputation Status, Lower Limb/Amputation Complications	6.737	6.497	6.322	6.207	6.195

TABLE 5—FINAL INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	253.927	252.583	251.467	251.462	251.464
Extremely Immature * Severity Level 4	154.510	153.094	151.930	151.820	151.808
Extremely Immature * Severity Level 3	33.920	32.887	32.017	31.768	31.749
Extremely Immature * Severity Level 2	33.920	32.887	32.017	31.768	31.749
Extremely Immature * Severity Level 1 (Lowest)	33.920	32.887	32.017	31.768	31.749
Immature * Severity Level 5 (Highest)	159.462	158.128	157.021	157.005	157.004
Immature * Severity Level 4	72.478	71.132	70.018	69.946	69.937
Immature * Severity Level 3	32.912	31.777	30.841	30.633	30.613
Immature * Severity Level 2	24.333	23.245	22.351	22.082	22.055
Immature * Severity Level 1 (Lowest)	24.333	23.245	22.351	22.082	22.055
Premature/Multiples * Severity Level 5 (Highest)	115.833	114.548	113.499	113.406	113.398
Premature/Multiples * Severity Level 4	27.460	26.234	25.253	25.043	25.026
Premature/Multiples * Severity Level 3	14.214	13.255	12.482	12.044	12.001
Premature/Multiples * Severity Level 2	7.992	7.259	6.638	6.009	5.940
Premature/Multiples * Severity Level 1 (Lowest)	5.323	4.790	4.246	3.652	3.600
Term * Severity Level 5 (Highest)	91.593	90.463	89.524	89.335	89.320
Term * Severity Level 4	14.962	14.042	13.315	12.830	12.788
Term * Severity Level 3	5.857	5.300	4.767	4.150	4.092
Term * Severity Level 2	3.574	3.148	2.666	1.994	1.935
Term * Severity Level 1 (Lowest)	1.546	1.321	0.916	0.449	0.423
Age1 * Severity Level 5 (Highest)	253.927	252.583	251.467	251.462	251.464

TABLE 5—FINAL INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2019 BENEFIT YEAR—Continued

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Age1 * Severity Level 4	154.510	153.094	151.930	151.820	151.808
Age1 * Severity Level 3	33.920	32.887	32.017	31.768	31.749
Age1 * Severity Level 2	33.920	32.887	32.017	31.768	31.749
Age1 * Severity Level 1 (Lowest)	33.920	32.887	32.017	31.768	31.749
Age 0 Male	159.462	158.128	157.021	157.005	157.004
Age 1 Male	72.478	71.132	70.018	69.946	69.937

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/description
Extremely Immature	Extremely Immature Newborns, Birth weight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750–999 Grams.
Immature	Premature Newborns, Including Birth weight 1,000–1,499 Grams.
Immature	Premature Newborns, Including Birth weight 1,500–1,999 Grams.
Premature/Multiples	Premature Newborns, Including Birth weight 2,000–2,499 Grams.
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight.
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.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.

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

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

d. Cost-Sharing Reductions Adjustments (§ 153.320)

We proposed to continue including an adjustment for the receipt of cost-sharing reductions in the model to account for increased plan liability due to increased utilization of health care services by enrollees receiving cost-sharing reductions (induced demand) in all States where HHS operates risk adjustment. The proposed cost-sharing reductions adjustment factors for the 2019 benefit year were unchanged from those finalized in the 2018 Payment Notice. These adjustments would be effective for 2016, 2017, 2018, and 2019 risk adjustment, and would be multiplied against the sum of the demographic, diagnosis, and interaction factors, and enrollment and prescription drug utilization factors (for the adult models). We are finalizing the cost-sharing reductions adjustment factors as proposed. See Table 8 for the list of final cost-sharing reductions adjustments for the 2019 benefit year.

Comment: Commenters supported our proposal to use the same cost-sharing reductions adjustment induced demand factors as prior years, noting that the use of these factors would promote stability and certainty in the markets, and supported making updates in 2020 to the induced demand factors based on EDGE enrollee-level data. One commenter requested that HHS maintain the induced demand factors of 1.12 for wrap-around, premium assistance plans for Massachusetts, as established in the 2014 Payment Notice and used by Massachusetts for the 2014, 2015 and 2016 benefit years.

Response: We are finalizing the cost-sharing reductions adjustment induced demand factors as proposed. We anticipate proposing adjustments to the cost-sharing reductions adjustment induced demand factors in the annual HHS notice of benefit and payment parameters for the 2020 benefit year based on enrollee-level EDGE data. Consistent with the approach outlined in the final 2017 Payment Notice, we will continue to use cost-sharing reductions adjustment factors of 1.12 for all Massachusetts wrap-around plans in the risk adjustment transfers calculation, as all of Massachusetts' cost-sharing plan variations have actuarial values above 94 percent.

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

e. Model Performance Statistics (§ 153.320)

To evaluate model performance, we examined each model's R-squared statistic 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 ratios are in the range of published estimates for concurrent risk adjustment models.[17] Because we are blending the coefficients from separately solved models based on 2014 and 2015 MarketScan® data and 2016 enrollee-level EDGE data, we are publishing the R-squared statistic for each model and benefit year separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 9.

[17] Winkleman, Ross and Syed Mehmud. ''A Comparative Analysis of Claims-Based Tools for Health Risk Assessment.'' Society of Actuaries. April 2007.

TABLE 9—R-SQUARED STATISTIC FOR FINAL HHS RISK ADJUSTMENT MODELS

Risk adjustment model	R-squared statistic		
	2014 MarketScan®	2015 MarketScan®	2016 Enroll-level EDGE
Platinum Adult	0.4221	0.4212	0.4283
Platinum Child	0.293	0.3314	0.3099
Platinum Infant	0.3284	0.3329	0.3239
Gold Adult	0.4179	0.4164	0.4228
Gold Child	0.2883	0.3269	0.3053
Gold Infant	0.3264	0.3309	0.3201
Silver Adult	0.4143	0.4123	0.4181
Silver Child	0.2841	0.3227	0.3013
Silver Infant	0.325	0.3295	0.317
Bronze Adult	0.4117	0.4095	0.4152
Bronze Child	0.2805	0.3188	0.2978
Bronze Infant	0.3247	0.3292	0.3154
Catastrophic Adult	0.4115	0.4094	0.4145
Catastrophic Child	0.2803	0.3186	0.2971
Catastrophic Infant	0.3247	0.3292	0.3151

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

i. Accounting for High-Cost Risk Pool in the Transfer Formula

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 high-cost risk pool payments and charges) will be calculated after issuers have completed risk adjustment data reporting. The payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, HHS will calculate separate transfer amounts for each rating area in which a plan operates).

The risk adjustment transfer formula generally calculates the difference between the revenues required by a plan, based on the health risk of the plan's enrollees, and the revenues that a plan can generate for those enrollees. These differences are compared across plans in the State market risk pool and converted to a dollar amount based on the Statewide average premium. Thus, each plan in the risk pool receives a risk adjustment payment or charge designed to compensate for risk for a plan with average efficiency. Scaling the risk adjustment transfers by the Statewide average premium, as opposed to, for example, the plan's own premium, minimizes issuers' ability to manipulate their transfers by adjusting their own plan premiums, and results in a calculation of equal payments and charges, ensuring that risk adjustment transfers for the entire market sum to zero.

In the absence of additional funding, we established, through notice and comment rulemaking,[18] risk adjustment as a budget neutral program in order to provide certainty to issuers regarding risk adjustment payments and allow them to set rates based on those expectations. Adopting an approach that would not result in balanced payments and charges would create considerable uncertainty for issuers regarding the proportion of risk adjustment payments they could expect to receive from the Federal government. Additionally, in establishing the HHS-operated risk adjustment program, HHS could not have relied on the potential availability of general appropriation funds without creating uncertainty for issuers in the amount of risk adjustment payments they could expect, or reducing funding available for other programs. Relying on each year's budget would have required HHS to delay setting the parameters for any risk adjustment payment proration rates well after the plans were in effect for the applicable benefit year. HHS also would not have been able to rely on any potential State budget appropriations for States that elected to operate a State-based risk adjustment program as such funds would not have been available for purposes of administering the HHS-operated risk adjustment program. Without the adoption of a budget neutral framework, HHS would have needed to assess a charge, or otherwise collect additional funds, or prorate payments based on the charges collected to balance the risk adjustment transfers. This uncertainty would conflict with the overall goals of the risk adjustment program: to stabilize premiums and reduce incentives for issuers to avoid enrolling individuals with higher than average actuarial risk.

The State payment transfer formula in the HHS risk adjustment methodology is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the State payment transfer formula would be multiplied by each plan's total billable member months for the benefit year to determine the total payment due to 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 or payment assessed for an issuer in a State market risk pool based on plan liability risk scores, in the 2018 Payment Notice, we added to the risk adjustment methodology additional transfers that would reflect the payments and charges assessed with respect to the high-cost risk pool. To account for costs associated with exceptionally high-risk enrollees, we added transfer terms (a payment term and a charge term) that would be calculated separately from the State transfer formula in the HHS risk adjustment methodology. Beginning for the 2018 benefit year, we added one term that reflects 60 percent of costs above $1 million ($HRP_i$, in the total plan transfer calculation described below), and another term that reflects a percent of premium adjustment to fund the high-cost risk pool and maintain the

[18] See, for example, Standards Related to Reinsurance, Risk Corridors and Risk Adjustment. Proposed Rule, 76 FR 41938 (July 15, 2011); Standards Related to Reinsurance, Risk Corridors and Risk Adjustment. Final Rule, 77 FR 17232 (March 23, 2012); and HHS Notice of Benefit and Payment Parameters for 2014. Final Rule, 78 FR 15441 (March 11, 2013).

balance of payment and charges within the risk adjustment program. The percent of premium adjustment factor applied to a plan's total premium amounts results in the same adjustment as a percent of PMPM premium adjustment factor applied to a plan's PMPM premium amount and multiplied by the plan's number of billable member months. For this calculation, we will use a percent of premium adjustment factor that is applied to each plan's total premium amounts, rather than the percent of PMPM premium adjustment factor described in 2018 Payment Notice and the proposed rule, for simplicity; and, as detailed above, we note that the mathematical outcome is the same. The percent of premium adjustment factor ($HRPC_m$) is determined based on the sum of payments for the high-cost risk pool enrollees divided by the sum of premiums in the respective high-cost risk pool market (m), nationally—one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market. The percent of premium adjustment factor is multiplied by the plan's total premium ($HRPC_m \cdot P_i$).

For the 2019 benefit year, we are finalizing the proposed policy to maintain this adjustment to the risk adjustment transfers with the threshold of $1 million and a coinsurance rate of 60 percent, as finalized for the 2018 benefit year.

Comment: In addition to the comments discussed above, one commenter requested that the high-cost risk pool adjustment factors be included in the risk adjustment formula.

Response: We have included a calculation for the total plan transfer amount below to illustrate the inclusion of the high-cost risk pool adjustment terms in the HHS risk adjustment methodology. As noted above, these terms will be applied within the high-cost risk pool markets nationally—one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market. We are finalizing the high-cost risk pool adjustment parameters for the 2019 benefit year as proposed.

ii. Administrative Cost Reduction to Statewide Average Premium

Additionally, we proposed to continue the policy finalized in the 2018 Payment Notice to reduce the Statewide average premium, the cost scaling factor in the risk adjustment transfer formula, by 14 percent to account for the proportion of administrative costs that do not vary with claims for the 2019 benefit year and future benefit years until changed in rulemaking. As a note, we have previously defined the cost scaling factor, or the Statewide average premium term, as the sum of average premium per member month of plan (P_i) multiplied by plan i's share of Statewide enrollment in the market in the risk pool (s_i). For the 2019 benefit year, the Statewide average premium, which will also be used for the transfer calculation for the 2018 benefit year, will be adjusted to remove a portion of the administrative costs as follows:

$$\bar{P}_S = (\Sigma_i(s_i \cdot P_i)) * 0.86$$

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.

We are finalizing the policy to reduce the Statewide average premium in the risk adjustment formula by 14 percent, as proposed, for the 2019 benefit year and future benefit years until changed in rulemaking.

Comment: Most commenters supported our proposal to continue to remove a portion of the administrative costs from the Statewide average premium factor of the risk adjustment transfer formula. Other commenters requested HHS publish the methodology used to create the 14 percent reduction from the MLR data. One commenter suggested HHS increase the reduction to 16 percent and another commenter requested HHS set the 14 percent reduction as the floor. Another commenter suggested HHS should set the factor closer to the market average of administrative costs, or allow the level to vary with issuers' claims experience.

Response: As we noted in the 2018 Payment Notice, we analyzed administrative and other non-claims expenses, including quality improvement expenses, taxes and fees, and non-claims costs, 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 reductions 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 that does not vary with claims is 14 percent. We continue to believe that this percentage represents the mean administrative cost percentage that does not vary with claims in the individual and small group markets, and represents a reasonable percentage of administrative costs on which risk adjustment transfers should not be calculated. Based on this analysis, we are finalizing the policy as proposed to reduce the Statewide average premium factor of the risk adjustment formula by 14 percent. Allowing the factor to vary with claims experience could lead to gaming and risk selection, as issuers with lower risk would receive lower charges if their administrative costs are relatively higher. Therefore, we will continue to reduce the Statewide average premium factor of the risk adjustment formula by the same percentage for all issuers.

iii. State Flexibility

The HHS risk adjustment payment transfer formula generally transfers amounts from issuers with lower than average actuarial risk to those with higher than average actuarial risk. Risk adjustment is widely used in health insurance markets, and is recognized as a critical measure in mitigating the effects of adverse selection, ensuring financial viability of plans that enroll a higher proportion of high-risk enrollees, and fostering competitive health insurance markets. The State transfer formula in the HHS-operated risk adjustment program is scaled with the Statewide average premium in the applicable State market. In the 2018 Payment Notice, we noted that compared to other scaling factors, such as plans' own premiums, our analyses found that the Statewide average premium proves to be a more appropriate means of scaling the transfers for differences in relative actuarial risk, particularly in the context of a budget-neutral system. As noted in the above section, beginning with the 2018 benefit year, we also adopted an administrative cost adjustment to the Statewide average premium to remove a portion of administrative costs that did not vary based on claims differences from the Statewide average premium and base the transfers on the portion of the premiums that vary with claims.[19] We continue to believe the Statewide average premium, as adjusted, is a reasonable metric to measure the costs of adverse selection. Based on our experience operating the risk

[19] 81 FR 94099, 94100. (December 22, 2016). Available at *https://www.gpo.gov/fdsys/pkg/FR-2016-12-22/pdf/2016-30433.pdf.*

adjustment program, HHS has become aware that certain issuers, including some new, rapidly growing, or smaller issuers, owed substantial risk adjustment charges that they did not anticipate. HHS has had a number of discussions with issuers and State regulators on ways to encourage new participation in the health insurance markets and mitigate the effects of substantial risk adjustment charge amounts. We believe that a robust risk adjustment program that addresses concerns of risk selection is critical to the proper functioning of health insurance markets. However, we recognize that States are the primary regulators of their insurance markets. In the May 2016 Interim Final Rule,[20] HHS recognized some State regulators' belief that reducing the magnitude of risk adjustment charge amounts could be beneficial to the insurance markets in their States. For some States, an adjustment to risk adjustment transfers calculated under the HHS-operated risk adjustment program might more precisely account for cost differences attributable to adverse selection in the respective State market risk pools. We encouraged States to examine whether any local approaches under State legal authority are warranted to help ease the transition for new entrants to the health insurance markets and mitigate the effects of large risk adjustment charge amounts. In the small group market, employers select the plans offered to their employees and often pay a significant portion of employees' premiums to encourage enrollment. Depending on the participation rules and market dynamics within a particular State, risk selection can be significantly less in a State's small group market compared to its individual market. The HHS methodology calculates relative risk scores between issuers in a State market, and in the case of the small group market, the differences between risk scores for issuers within State markets are generally smaller, leading to a smaller magnitude of risk adjustment transfers in the small group market as compared to the individual market. Certain States have opined that the HHS risk adjustment methodology, which is calibrated on a national dataset and does not take into account the effect of State-specific laws and rating rules, in some circumstances may not precisely account for risk differences for their particular State. We note that States have the statutory authority to operate their own State risk adjustment program under a Federally certified alternate risk adjustment methodology and are free to exercise that authority to develop a risk adjustment program tailored to the markets in their State. However, we also believe that allowing certain State-specific adjustments to the HHS risk adjustment methodology can account for the effect of State-specific rules without the necessity for States to undertake operation of their own risk adjustment program.

In the case of small group markets, where States can demonstrate that the differential risk profiles observed in the small group market plans in that State are attributable to factors other than systematic risk selection, and adverse selection risk is mitigated by the small group market dynamics, such as those described above, we proposed to permit States' primary insurance regulators to request a percentage reduction in the calculation of the risk adjustment transfer amounts in the small group market in their State, beginning for the 2019 benefit year.

We proposed that HHS would require any State that seeks this flexibility to submit its proposal for an adjustment to the Statewide average premium in the small group market within 30 calendar days after publication of the proposed HHS notice of benefit and payment parameters for the applicable benefit year, in order to permit issuers to incorporate any such adjustment into their proposed rates. In order to promote transparency and solicit feedback from consumers and stakeholders on the proposed reductions to the HHS risk adjustment transfer formula, we proposed HHS would publish the requested State reduction percentages for public comment in guidance while it begins its initial review of the State requests. We proposed that HHS would then make final determinations on State requests by March 1 of the benefit year prior to the applicable benefit year, in time for issuers' initial rate setting deadline. The proposed timing of the State adjustment request, publication of HHS guidance setting forth the requested State reduction percentages, public notice and comment period and HHS approval process would permit plans to incorporate approved adjustments in their rates for the applicable benefit year.

Under the proposal, HHS would consider requests from State regulators to reduce the calculation of the Statewide average premium used in the HHS risk adjustment transfer formula in the small group market by up to 50 percent for the applicable benefit year. We sought comment on all aspects of this proposal for the small group market, including the size of the reduction, the timing of the request submission, what evidence States should be required to provide, and what procedural requirements should be established.

We also sought comment on whether we should establish a similar process through which States could request a reduction to the calculation of risk adjustment transfers in the individual market. Although adverse selection in the individual market is not mitigated by group enrollment or minimum participation requirements as is the selection in the small group market, we recognized that a State may believe the HHS risk adjustment methodology, which is calibrated on a national dataset, may not precisely account for relative actuarial risk differences in its individual market risk pool. We sought comment on whether, if a State can demonstrate such a difference in calculated relative actuarial risk, we should reduce States' administrative burden in operating its own risk adjustment program by allowing some flexibility in the HHS risk adjustment methodology to the extent permissible under the statute. Therefore, we sought comment on what individual market features would justify such a reduction, and what additional submissions a State should provide in order to justify such a departure for that market.

We recognize that it is possible the HHS risk adjustment methodology, which is calibrated on a national dataset and does not take into account State-specific rules or market dynamics, may not precisely account for relative actuarial risk differences in certain States' individual, small group or merged markets, and those State-specific rules or other relevant factors could support a reduction to transfers in that State's individual, small group or merged market. To accommodate situations where there may be such differences in State factors compared to the national norm, HHS is finalizing the policy to provide States the flexibility to request a reduction to the otherwise applicable risk adjustment transfers in the individual, small group or merged market by up to 50 percent with some modifications, outlined below, in response to comments. In States that request a reduction to transfers, the reduction percentage up to 50 percent, if approved by HHS, would be applied to the plan PMPM payment or charge transfer amount (T_i in the State transfer formula below), beginning with the 2020 benefit year. We are amending § 153.320 to add a new paragraph (d) to capture this State flexibility to request

[20] 91 FR 29146, 29152. (May 11, 2016). Available at *https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11017.pdf.*

reduction to transfers in the individual, small group or merged market. States requesting such reductions must submit evidence and analysis to HHS identifying the State-specific rules or market dynamics that warrant an adjustment and demonstrating the actuarial risk differences in plans in the applicable State market are attributable to factors other than systematic risk selection, as well as substantiating the amount of the transfer reduction requested. For example, a State could submit evidence and analysis detailing the effect of a State rating rule that might lead to a portion of the State average premium that does not precisely reflect the cost of relative differences in actuarial risk in the individual, small group or merged market. The State request must specify in detail the State-specific rules or market dynamics that warrant an adjustment to the HHS risk adjustment methodology to more precisely account for the expected cost of relative risk differences in the State's individual, small group or merged market. Additionally, the State must submit evidence and analysis justifying the reduction percentage requested. To justify the amount of the transfer reduction requested, the State's evidence and analysis must explain how the requested transfer adjustment was determined by outlining the set of State-specific factors and the percentage reduction warranted to account for those factors in the State's market; or alternatively, it must demonstrate the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer's or issuers' reduced payments. In the latter case, a State must demonstrate that the reduced risk adjustment payments would result in less than a 1 percent increase in the affected issuer's or issuers' premiums. We are adding paragraph (d)(1) to § 153.320 to specify the submission requirements for the State requests, as outlined above. We are also adding paragraph (d)(4) to specify that HHS will approve the State requests if, based on a review of the information submitted as part of the State request, along with other relevant factors, including the premium impact of the transfer reduction for the State market, and relevant public comments, HHS determines that the State-specific factors warrant an adjustment and the State request includes support justifying the percentage reduction requested or includes information demonstrating that the reduction to transfers would have a *de minimis* impact as described above. As reflected in paragraph (d)(4)(ii) to § 153.320, HHS may approve a reduction amount lower than that requested by the State if the supporting evidence and analysis do not fully support the percentage reduction requested. In response to commenters' concerns about market impacts on issuers with higher than average actuarial risk, HHS will assess other relevant factors, including the premium impact of the transfer reduction for the State market.

The approved reductions will be made on the calculated risk adjustment transfer amounts, rather than the Statewide average premium as proposed, prior to the application of the high-cost risk pool adjustments (high-cost risk pool payment and charge amounts). Applying the reduction is simply a mathematical operation and applying it on the otherwise calculated transfer amounts will result in the same final transfer amount mathematically as if the reduction was applied to the Statewide average premium, but will simplify the process for submission, review and calculation of the reductions to transfers.

We are finalizing modified timelines and adding paragraphs (d)(2) and (d)(3) at § 153.320 to capture the timeframe for submission and publication of State requests to reduce transfers in the individual, small group and merged markets in response to comments. We are not finalizing this proposed policy for the 2019 benefit year, in order to accommodate the evidence and analysis required and to provide more time for the development and review of such requests. Additionally, we believe the requests should be published in the relevant benefit year's proposed HHS notice of benefit and payment parameters to seek comment from relevant stakeholders. As such, consistent with paragraph (d)(2), beginning with 2020 and future benefit years, States must submit requests with the supporting evidence and analysis by August 1st, 2 calendar years prior to the beginning of the applicable benefit year (for example, August 1, 2018, for the 2020 benefit year) to *RARIpaymentoperations@cms.hhs.gov* with the subject ''[Insert applicable benefit year] State request to reduce risk adjustment transfers.'' This modified timeline responds to comment received and provides States the opportunity to review the most recent year of risk adjustment transfers data in determining the requested percentage reduction to transfers and when submitting the supporting evidence. As outlined in paragraph (d)(3), we will publish the 2020 and future benefit year requests in the respective benefit year's proposed HHS notice of benefit and payment parameters and make the supporting evidence available to the public in order to seek public comment, and will publish any approved State reduction requests or denied State reduction requests in the respective benefit year's final HHS notice of benefit and payment parameters.

Comment: A few commenters supported providing States the flexibility to request transfer reductions in the individual, small group and merged markets, noting that the risk adjustment program has been a barrier to entry for issuers in certain States. These commenters stated such a reduction to transfers could enable issuer participation in the individual, small group and merged markets. Additionally, these commenters noted the expense of operating a State-based risk adjustment program limits States from establishing their own risk adjustment methodologies. A few State regulators noted their intent to consider the reduction and potential impacts for future benefit years, and requested ''off-cycle'' dialogues with HHS to consider such reductions.

Several commenters supported the reduction to transfers only for the small group market, noting that the adverse selection in the individual market requires the risk adjustment program to ensure competitive and stable markets. These commenters noted such a reduction to transfers would be detrimental to market stability in the individual market, with one commenter noting that unexpectedly large charges were a risk for issuers in the early years of the program and the markets have since stabilized. A few commenters noted that HHS should allow States to permit reductions in merged markets as well, while others noted this policy should not be made available in merged markets given the impact on individual market dynamics in the merged market States. Yet a few commenters suggested the flexibility be allowed across the individual, small group and merged markets. One commenter noted that such a reduction would be appropriate in the individual market as well to reduce carrier-specific transfers to adjust for administrative costs, limit distortions due to how many family members are counted toward premiums, or prevent perverse incentives to avoid care management or network variations that lower costs.

Other commenters did not support a reduction to the risk adjustment transfers, stating the reduction to

transfers would undermine affordability of plans with sicker patients. Commenters were also concerned that providing such reductions would encourage risk selection behavior by issuers, encourage risk segmentation in the markets, reduce effectiveness of the risk adjustment program, lead to higher premiums for small employers and consumers where issuers with higher than average risk are not adequately compensated for their risk, reduce choices for consumers even further, and destabilize the markets. Commenters stated the importance of the risk adjustment program in promoting competition in the individual, small group, and merged markets by mitigating the issuers' risk of adverse selection. Commenters noted that the risk adjustment methodology already adjusts for a multitude of State- and rating area-specific factors as the methodology calculates risk scores at the individual level, and transfers at the rating area level. A few commenters also noted that maintaining risk adjustment as is would become increasingly important, especially if HHS were to move forward with the EHB flexibilities discussed elsewhere in this rule, as issuers could enroll differential risk enrollees based on the EHBs offered. Commenters noted that if HHS finalizes the policy to permit requests for adjustments in the small group market, issuers would no longer have an incentive to enroll all types of employers and could target healthier employers in certain sized employers through marketing and other strategies. Additionally, commenters noted that if relative risk for health conditions in an individual State is substantially different than the national average, it is not clear that a reduction of 50 percent to risk adjustment transfers would be appropriate, and the State ought to consider developing its own risk adjustment model to address significant deviations in the State's risk profiles that deviate from the national average or use the section 1332 of PPACA waiver process to implement a reinsurance type program. Commenters agreed with HHS that the smaller magnitude of transfers in the small group market than in the individual market indicates the lower adverse selection risk in the small group market, but stated that the HHS risk adjustment program is properly calibrated for this lower risk of adverse selection in the small group market. Commenters noted that while employer contributions, employer choice of benefit plans, and participation rules mitigate selection in the small group market, the risk adjustment methodology appropriately accounts for these market differences because the lower adverse selection is reflected in the lower risk score differential. Commenters noted that Oliver Wyman, American Academy of Actuaries, and HHS's studies have all shown the risk adjustment program is working as intended in mitigating adverse selection. A few commenters also noted a study by Oliver Wyman [21] that suggested reducing transfers by up to 50 percent may make the risk adjustment program less effective in compensating plans with higher than average risk and would therefore increase issuers' risk selection incentives. Additionally, one commenter noted that the significant adjustments to the risk adjustment program being implemented for the 2017 and 2018 benefit years should be evaluated prior to making any additional changes.

Response: In certain State individual, small group or merged markets, it is possible that the HHS risk adjustment methodology, which is calibrated on a national dataset, may not reflect State-specific factors that could result in relative risk differences in the State's market(s) compared to the national norm. Such unique State rules or other relevant factors could support a reduction to the otherwise applicable risk adjustment transfers to more precisely account for the differences in relative actuarial risk in the State's individual, small group or merged market. We agree with commenters that, in such instances, allowing certain State-specific adjustments to the otherwise applicable transfers can tailor the HHS-operated risk adjustment program to the particularities of a State's individual, small group or merged market without requiring the State to undertake operation of its own risk adjustment program or pursue a section 1332 waiver to implement a reinsurance program. In those circumstances, in which States can provide evidence and analysis showing the State-specific rules or market dynamics that warrant an adjustment to the HHS risk adjustment methodology to more precisely account for the relative risk differences in the State's market, HHS will consider requests to reduce transfers beginning with the 2020 benefit year. We agree with commenters that the small group market features, such as employers' selection of plans, and minimum participation and contribution rules, that lead to lower risk of adverse selection compared to the individual market are addressed in the current HHS risk adjustment methodology. Therefore, a State requesting a reduction of up to 50 percent of transfers in its small group market must provide supporting evidence and analysis outlining the State-specific factors that warrant an adjustment to the HHS risk adjustment methodology to more precisely account for relative risk differences in that State market compared to the national norm, rather than demonstrating the factors that are addressed in the current methodology. States must also justify the amount requested by outlining how the percentage reduction would more precisely account for risk differences in the State's individual, small group or merged market or by demonstrating that the reduction in risk adjustment payments would have a *de minimis* effect on the necessary premium increase to cover the affected issuer or issuers' reduced payments. HHS will not approve State requests for reduction to transfers based on factors in the State's individual, small group or merged market that are addressed by the current HHS risk adjustment methodology.

We appreciate commenters' concerns about extending the flexibility to the individual or merged markets. We believe that those enrolled in the individual or merged markets typically have higher actuarial risk, risk selection, and risk segmentation in plan selection than those enrolled in the small group market, and risk adjustment transfers are particularly required in these markets to mitigate issuers' risk of adverse selection and incentives to avoid risk. However, we recognize that, just as with certain States' small group markets, it is possible that certain factors unique to the States' individual or merged market, such as State rating requirements, could support a reduction to transfers in that State market, and therefore are finalizing the State flexibility to request reduction to otherwise applicable risk adjustment transfers in the individual and merged markets as well. We note that guaranteed availability, guaranteed renewability, as well as the non-discrimination provisions at §§ 147.104(e), 147.110 and 156.125(a), provide protections against potential employment of marketing practices or benefit designs that have the effect of avoiding less healthy employer groups, discriminating based on health conditions, or otherwise discouraging enrollment of individuals with significant health needs. Finally, allowing for the State flexibility for the 2020 benefit year, will allow us to assess

[21] Available at *http://health.oliverwyman.com/transform-care/2017/11/risk_adjustment.html.*

the impact of the changes made to the risk adjustment program beginning for the 2017 and 2018 benefit years, and we intend to monitor the impact of the changes to the risk adjustment program. States will also have the opportunity to assess the effects of the risk adjustment model changes implemented for the 2017 benefit year prior to submitting any State requests to reduce transfers for the 2020 benefit year.

Comment: A few commenters noted the extent of the reduction seemed arbitrary or too high, and requested HHS explain how it chose the 50 percent adjustment threshold. Commenters also suggested that HHS should finalize a smaller percentage reduction if it finalizes the proposal. One commenter stated that it is equally likely that a State needs to increase the risk adjustment transfers and HHS ought to allow for this type of a request as well.

Response: We are clarifying that the adjustment applicable to a State individual, small group or merged market would not necessarily be 50 percent, but would be the amount, up to 50 percent, justified by the State request. HHS reviewed transfers, the potential impact of such a reduction on market premiums and the proportion of the transfers as a percent of issuers' payments when considering the appropriate threshold. We believe that an adjustment of up to 50 percent, justified by State-specific factors, represents a reasonable balance between adjustment for actuarial risk based on a national methodology and recognition of unique State-specific factors that suggest that actuarial risk difference is not precisely accounted for by the national methodology. In instances where a State believes that an increase to risk adjustment transfers would be appropriate, State regulators under their own State authority could take actions outside of this flexibility to ease the transition for new entrants and/or mitigate the effects of large risk adjustment transfers. States can also elect to establish and operate the PPACA risk adjustment program. Additionally, we do not believe that an increase to the transfers could be deemed necessary as the current methodology would be sufficient to calculate the transfers necessary to compensate for the relative actuarial risk differences scaled to the average cost for the State market.

Comment: Some commenters noted that States should be required to submit an actuarially certified report demonstrating the extent to which the transfers overstate differentials in uncompensated predicted risk, the method of estimating the requested adjustment factor, an attestation that the percent reduction requested results in a risk adjustment methodology that complies with Actuarial Standard of Practice (ASOP) 12, Risk Classification, and an assessment of adverse selection effects that may result from the implementation of the payment transfer reduction. A few commenters also suggested HHS require States to provide evidence that issuers with large charges in the risk adjustment program did not have issues related to coding, operational data submission, incorrect rate setting, or suboptimal provider contracting and medical expenses that contributed to their risk adjustment results rather than differences in the State risk pool compared to the national average.

Response: We agree with commenters that States should be required to submit evidence and analysis supporting the requests for reductions to transfers in the individual, small group or merged market, and therefore, are requiring that States requesting a reduction in risk adjustment transfers submit supporting evidence and analysis to HHS. We are requiring States to submit supporting evidence and analysis demonstrating the State-specific rules or relevant factors that warrant an adjustment to more precisely account for risk differences in the State's individual, small group or merged market. Additionally, we are requiring the States to justify the percentage reduction requested based on supporting evidence and analysis that demonstrate how the adjustment would accommodate the State-specific factors and more precisely account for risk differences in the State's individual, small group or merged market or how the reduction would have a *de minimis* effect on the percent of premium increase necessary to cover the reduced payments to the affected issuers. We considered but are not requiring States to submit actuarially certified reports, an attestation, or simulation of the potential effects of the requested reduction as part of their requests. We determined that to ensure issuers are adequately compensated for the actuarial risk of their enrollees and do not have incentives to avoid higher risk enrollees, the State regulators need to submit evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State's market, and justifying the percent reduction requested based on the State factors or a *de minimis* effect. Additionally, HHS will publish the requests in the proposed rulemaking for the respective benefit year and make the supporting evidence publicly available for comment, and consider the relevant comments in its review. We note that the data integrity issues flagged by commenters are assessed during the EDGE server data quality and quantity assessments, as well as through the risk adjustment data validation program.

Comment: Commenters generally requested additional time for States to submit requests. Commenters noted that if HHS were to move forward with this proposal, the agency should consider implementing the policy in 2020, as this policy will affect small group policies that are offered starting on and after January 1, 2018, as small group plans are not offered on a calendar year basis, and quarterly rate filings, which would already be in effect, would adversely affect these plans. One commenter suggested HHS set the State request deadline at 30 days after the June 30, 2018 risk adjustment summary report or request State submissions for the 2020 benefit year before August 2018. Other commenters suggested HHS allow States to provide the requests and any supporting material 60 days or 75 days from the publication of the proposed rule. Most commenters agreed that HHS should provide an opportunity for comment for the issuers and other stakeholders in the States that make such requests before approving or denying the reduction. One commenter also noted States require additional time to develop their respective requests and issuers require additional time to communicate their position with State regulators than that allowed by the timing in the proposed rule.

Response: We appreciate commenters' suggestions regarding timing, and are finalizing modified timelines for States to request a reduction to the risk adjustment transfers in response to these comments. As discussed above, States will be permitted to request these adjustments to transfers beginning for the 2020 benefit year. We agree with commenters that small group market issuers may have already begun policies that would be affected by a reduction to transfers for the 2019 benefit year, and issuers may need additional time to incorporate changes and reflect any reduction to transfers in their rates. Additionally, for the individual, small group and merged markets, we also considered the amount of time State regulators would require to assemble the supporting evidence and analysis to justify their requests and to consider the annual HHS June 30th risk adjustment transfers calculation results in determining the State reduction request.

The timeframe we are adopting in response to comments requires States to submit the request by August 1st, 2 calendar years prior to the applicable benefit year which will allow States to submit documentation to satisfy the supporting evidence and analysis requirements in this rule and incorporate the most recent available year of HHS risk adjustment transfer results in the State's request. Additionally, we agree with commenters about the importance of providing issuers and stakeholders an opportunity to comment on the request and supporting evidence. As outlined in paragraph (d)(3) of § 153.320, HHS will publish the requests in the respective benefit year's proposed HHS notice of benefit and payment parameters and make the supporting evidence available to the public to seek comment from relevant stakeholders, and will publish any final approved or denied reduction amounts in the final HHS notice of benefit and payment parameters for the respective benefit year. The modified timelines and supporting evidence requirements finalized in this rule, including the delayed application of this policy until the 2020 benefit year, are intended to provide States, issuers and other stakeholders with sufficient opportunity to develop, submit and comment on these reduction requests prior to finalization of the HHS-operated risk adjustment methodology for the applicable benefit year.

Comment: A few commenters noted that New York has already taken action to reduce transfers under the State's authority, and requested clarification whether other States could continue to take steps under existing State authority. One commenter noted that the New York adjustment could be seen as permitting States to make adjustments without HHS approval and requested clarification that States making adjustments to the risk adjustment formula must first obtain approval from HHS under the risk adjustment program prior to implementing any State-specific adjustments.

Response: As we noted above, States are the primary regulators of their insurance markets, and as such, we encourage States to examine whether any local approaches under State legal authority are warranted to help ease the transition for new participants to the health insurance markets. States that take such actions and make adjustments do not generally need HHS approval as these States are acting under their own State authority and using State resources. However, the flexibility finalized in this rule involves a reduction to the risk adjustment transfers calculated by HHS and will require HHS review as outlined above.

iv. The Payment Transfer Formula

The finalized State payment transfer formula for the 2019 benefit year is unchanged from what was finalized in the 2014 Payment Notice (78 FR 15430 through 15434). We believe it useful to republish the formula in its entirety. 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. The State payment transfer calculation that is part of 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 State enrollment;

The denominator is summed across all plans in the risk pool in the market in the State.

The difference between the two premium estimates in the State payment transfer calculation determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. 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 the risk adjustment transfer calculation, not including the national high-cost risk pool payments and charges. This resulting PMPM plan payment or charge is multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the State.

Beginning with the 2018 benefit year, the high-cost risk pool adjustment amount will be added to the plan transfers (payment or charge) to account for: (1) The payment term, representing the portion of costs above the threshold reimbursed to the issuer for high-cost risk pool payments (HRP_i), if applicable, and (2) the charge term, representing a percent of premium adjustment, which is the product of the high-cost risk pool adjustment factor ($HRPC_m$) for the respective national high-cost risk pool *m* (one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market), and the plan's total premiums (P_i). As we noted above, the percent of premium adjustment factor applied to a plan's total premium amounts results in the same adjustment as a percent of PMPM premium adjustment factor applied to a plan's PMPM premium amount and multiplied by the plan's number of billable member months. For this calculation, we will use a percent of premium adjustment factor that is applied to each plan's total premium amounts, rather than the percent of PMPM premium adjustment factor for simplicity; and reiterate that the mathematical outcome is the same.

With the high-cost risk pool adjustment amount, the total plan transfers would be calculated as the product of the plan PMPM transfer amount (T_i) multiplied by the plan's billable member months (M_i), plus the high-cost risk pool adjustments. The total plan transfer (payment or charge) amounts under the HHS risk adjustment payment transfer formula would be calculated as follows:

$$Total\ transfer_i = (T_i \cdot M_i) + HRP_i - (HRPC_m \cdot P_i)$$

Where:

T_i = Plan *i*'s PMPM transfer amount;
M_i = Plan *i*'s billable member months;
HRP_i = Plan i's total high-cost risk pool payment;
$HRPC_m$ = High-cost risk pool percent of premium adjustment factor for the respective national high-cost risk pool *m;*
P_i = Plan *i*'s total premium amounts.

In States that requested a reduction to transfers in the individual, small group or merged market, the reduction

percentage up to 50 percent, if approved by HHS for the applicable benefit year beginning with the 2020 benefit year, would be applied to the plan PMPM payment or charge transfer amount (T_i). This potential reduction to the PMPM transfer amounts is not shown in the risk adjustment transfer formula above.

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

HHS will conduct risk adjustment data validation under § 153.630 in any State where HHS is operating risk adjustment on a State's behalf.[22] 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 auditor for data validation. Set forth below are final amendments and clarifications to the risk adjustment data validation program in light of experience and feedback from issuers during the first pilot year.

i. Payment Adjustments for Error Rates

Under § 153.350(c), HHS may adjust risk adjustment payments and charges to all issuers of risk adjustment covered plans based on adjustments to the average actuarial risk of a risk adjustment plan due to errors discovered during risk adjustment data validation. Under the original risk adjustment data validation payment adjustment approach, all issuers of risk adjustment covered plans would receive an adjustment to payment transfers in the subsequent benefit year based on risk adjustment data validation audit results and using the audit-confirmed, issuer-specific risk score error rate. However, we believe that some variation and error should be expected in the compilation of data for risk scores, because providers' documentation of enrollee health status varies across provider types and groups. Our experiences with the Medicare Advantage risk adjustment data validation program and the HHS risk adjustment data validation pilot for the 2015 benefit year reinforce this belief.

To avoid adjusting all issuers' risk adjustment payments for expected variation and error, we proposed evaluating material statistical deviation in error rates beginning with 2017 benefit year risk adjustment data validation. In the proposed rule, we explained that we were considering adjusting an issuer's risk score only when the issuer's error rate materially deviates from a statistically meaningful value, such as the central tendency (a mean or typical value) of errors, nationally. When an error rate materially deviates from the central tendency, we proposed to apply the difference between the mean error rate or the confidence interval around the population's central tendency and the calculated error rate instead of the full error rate. If all error rates in a State risk pool do not materially deviate from the national central tendency of error rates, we proposed to not apply any adjustments to issuers' risk scores for that benefit year in the respective State risk pool.

We also noted that alternatively, HHS could evaluate error rates within each HCC, or groups of HCCs, and then only apply error rates to outlier issuers' risk scores within each HCC or group of HCCs. In evaluating the ''error rate'' of HCCs, or groups of HCCs, we mean the probability of an assigned HCC being found to be incorrect based on the risk adjustment data validation audit, or a ''failure rate.'' The percent of the EDGE risk score that is incorrect due to audit findings (that is, due to HCCs that could not be validated through audit), we consider to be the issuer's risk score error rate. For example, an issuer could have a 50 percent failure rate for an HCC, in that two of four instances of the HCC on EDGE could not be validated. The impact of HCC failure rates on an issuer's error rate will then depend on the magnitude of the missing HCC's coefficient and the incidence of that HCC in the audit sample.

We believe the implementation of any of the alternative evaluations and subsequent adjustments we proposed would streamline the risk adjustment data validation process, improve issuers' ability to predict risk adjustment transfers, and promote confidence and stability in the budget-neutral payment transfer methodology, while ensuring the integrity and quality of data provided by issuers.

We are finalizing the approach described above of using failure rates specific to HCC groups and subsequently adjusting the issuer's risk score when the issuer's failure rate for a group of HCCs is statistically different from the weighted mean failure rate, or total failure rate, for that group of HCCs for all issuers that submitted initial validation audits. We are selecting this approach based on comments received, which generally were more supportive of the HCC or HCC-grouping methodology for evaluating failure rates than an approach under which we would calculate a national overall error rate. Additionally, we believe determining outlier failure rates based on HCC groups mitigates gaming concerns raised by commenters in using a national error rate, and mitigates commenters' sample size concerns in using HCC-specific failure rates. Our simulations of failure rates by HCC group suggest that such an approach yields a more equitable measure to evaluate statistically different HCC failure rates affecting an issuer's error rate than an approach based on an overall failure rate, which may overly adjust issuers with abnormal distributions of certain HCCs due to their underlying populations rather than differences due to errors in diagnoses codes. Illustrations of the methodology we will use to evaluate failure rate differences by HCC group, calculate error rates based on failure rates, and apply error rates to risk scores are provided below.

Using data from the 2017 benefit year risk adjustment data validation, HHS will first calculate the failure rate for each HCC in issuers' initial validation audit samples as:

$$FR^h = 1 - \frac{Freq_IVA^h}{Freq_EDGE^h}$$

Where:

$Freq_EDGE^h$ is the frequency of HCC code h occurring on EDGE, which is the number of sampled enrollees recording HCC code h on EDGE.

$Freq_IVA^h$ is the frequency of HCC code h occurring in IVA results, which is the number of sampled enrollees with HCC code h on in IVA results.

FR^h is the failure rate of HCC code h.

HHS will then create three HCC groups based on the HCC failure rates derived in the calculation above. These HCC groups will be determined by first ranking all HCC failure rates and then dividing the rankings into three groups, weighted by total observations or frequencies, of that HCC across all issuers' initial validation audit samples, to assign each unique HCC in the initial validation audit samples to a high, medium, or low failure rate group with an approximately even number of observations in each group. That is, each HCC group may have an unequal number of unique HCCs, but the total

[22] Starting with the 2017 benefit year, no State has elected to operate a risk adjustment program. Therefore, HHS operates risk adjustment in all States.

observations in each group should be approximately equal based on total observations of HCCs reflected in EDGE data for all issuers' initial validation audit sample enrollees, to prevent small sample sizes for an HCC group for any issuer.

HHS will then compare each issuer's failure rate for each HCC group based on the number of HCCs validated in the initial validation audit, compared to the number of HCCs recorded on EDGE within that HCC group for the initial validation audit sample enrollees. The issuer's HCC group failure rate will be compared to the weighted mean failure rate, or total failure rate, for that HCC group. We calculate an issuer's HCC group failure rate as:

$$GFR_i^G = 1 - \frac{Freq_IVA_i^G}{Freq_EDGE_i^G}$$

Where:

$Freq_EDGE_i^G$ is the number of HCCs in group G in the EDGE sample of issuer i.

$Freq_IVA_i^G$ is the number of HCCs in group G in the IVA sample of issuer i.

GFR_i^G is i's group failure rate for the HCC group G.

We will also calculate the weighted mean failure rate and the standard deviation of each HCC group as:

$$\mu^*(GFR^G) = 1 - \frac{\sum Freq_IVA_i^G}{\sum Freq_EDGE_i^G}$$

$$Sd(GFR^G) = \sqrt{\frac{\sum_i Freq_EDGE_i^G * \left(GFR_i^G - \mu(GFR^G)\right)^2}{\sum_i Freq_EDGE_i^G}}$$

Where:

$\mu(GFR^G)$ is the weighted mean of GFR_i^G of all issuers for the HCC group G weighted by all issuers' sample observations in each group.

$Sd(GFR^G)$ is the standard deviation of GFR_i^G of all issuers for the HCC group G.

If an issuer's failure rate for an HCC group falls outside the confidence interval for the weighted mean failure rate for the HCC group, the failure rate for the issuer's HCCs in that group would be considered an outlier. We will use a 1.96 standard deviation cutoff, for a 95 percent confidence interval, to identify outliers. To calculate the thresholds to classify an issuer's group failure rate as outliers or not, the lower and upper limits are computed as:

$LB^G = \mu(GFR^G) - sigma_cutoff * Sd(GFR^G)$

$UB^G = \mu(GFR^G) + sigma_cutoff * Sd(GFR^G)$

Where:

sigma_cutoff is the parameter used to set the threshold for the outlier detection as the number of standard deviations away from the mean.

LB^G, UB^G are the lower and upper thresholds to classify issuers as outliers or not outliers for group G.

When an issuer's HCC group failure rate is an outlier, we will reduce (or increase) each of the applicable initial validation audit sample enrollees' HCC coefficients by the difference between the outlier issuer's failure rate for the HCC group and the weighted mean failure rate for the HCC group. Specifically, this will result in the sample enrollees' applicable HCC risk score components being reduced (or increased) by a partial value, or percentage, calculated as the difference between the outlier failure rate for the HCC group and the weighted mean failure rate for the applicable HCC group. The adjustment amount for outliers will be the distance between issuer i's Group Failure Rate GFR^i_G and the weighted mean $\mu(GFR^G)$, calculated as:

$$\text{If } GFR_i^G > UB^G \text{ or } GFR_i^G < LB^G:$$

$$\text{Then } Flag_i^G = \text{"}outlier\text{"} \text{ and } Adjustment_i^G = GFR_i^G - \mu(GFR^G)$$

$$\text{If } GFR_i^G \leq UB^G \text{ and } GFR_i^G \geq LB^G:$$

$$\text{Then } Flag_i^G = \text{"}not\ outlier\text{"} \text{ and } Adjustment_i^G = 0$$

Where:

$Flag_i^G$ is the indicator if issuer *i*'s group failure rate for group *G* locates beyond a calculated threshold that we are classifying issuers into "outliers" or "not outliers" for group *G*.

$Adjustment_i^G$ is the calculated adjustment amount to adjust issuer *i*'s EDGE risk scores for all sampled HCCs in group *G*.

The adjustment to an enrollee's total risk score is calculated as the ratio of the total adjusted risk score for individual HCCs to the total risk score components for individual HCCs. For example, if an issuer has one enrollee with the HIV/AIDS HCC and the issuer's HCC group adjustment rate is 10 percent (the difference between the issuer's group failure rate and the weighted mean failure rate) for the HCC group that contains the HIV/AIDS HCC, the enrollee's HIV/AIDS coefficient would be reduced by 10 percent. We calculate the total adjustment amount across all HCCs per enrollee as:

$$Adjustment_{i,e} = \frac{\sum_{hcc}\left(RS_{i_e}^{hcc,G} * Adjustment_i^G\right)}{\sum_{hcc}\left(RS_{i,e}^{hcc,G}\right)}$$

Where:

$RS_{i.e}^{hcc,G}$ is the risk score component of a single HCC (belonging to HCC group *G*) recorded on EDGE for enrollee *e* of issuer *i*.

$Adjustment_{i,e}$ is the calculated adjustment amount to adjust enrollee *e* of issuer *i*'s EDGE risk scores.

The adjusted risk score for enrollee *e* of issuer *i* is calculated as:

$AdjRS_{i,e} = EdgeRS_{i,e} * (1 - Adjustment_{i,e})$

Where:

$EdgeRS_{i,e}$ is the risk score for EDGE HCCs of enrollee *e* of issuer *i*.

$AdjRS_{i,e}$ is the adjusted risk score for sampled enrollee *e* of issuer *i*.

We will then calculate an issuer's error rate using the EDGE risk score and adjusted risk score for all enrollees in the sample (excluding enrollees with no HCCs). The weight w_e in the error rate calculation formula is obtained by the ratio of an enrollee's stratum size in the issuer's population to the number of sample enrollees in the same stratum as the enrollee, to extrapolate the sample adjusted risk scores and determine the issuer's risk score error rate. The formula to compute the error rate using the stratum weighted risk score for issuer *i* before and after the adjustment is shown as:

$$ErrorRate_i = 1 - \frac{\sum_e \left(w_e * AdjRS_{i,e}\right)}{\sum_e \left(w_e * EdgeRS_{i,e}\right)}$$

Where:

$$w_e = \frac{stratum\ size\ in\ population}{number\ of\ sample\ enrollees\ of\ the\ stratum}$$

$ErrorRate_i$ is the final error rate for issuer *i* based on sampled enrollees.

The risk score error rate would then be applied to the subsequent benefit year calculated plan level risk scores, to adjust the issuer's plan level risk scores before risk adjustment transfers are calculated, unless the issuer exited the market during or at the end of the benefit year being audited.[23]

Comment: Most commenters supported the proposal to only adjust issuers' risk scores if their failure or error rates materially deviate from a statistical mean, with some noting that this approach could help streamline risk adjustment data validation and increase market stability. A few commenters noted the complexity of the approach and requested more information on various aspects of the proposed approach, such as the definitions of material deviation and statistically meaningful value, the methodology that HHS would use to evaluate material deviation, the calculation of national or HCC-level error rates, and the sufficiency of the sample sizes under the HCC or group of HCCs approach.

Response: As outlined above, for the purposes of risk adjustment data validation, we will determine that an issuer's failure rate is statistically different if the issuer's failure rate for a particular HCC group is more than 1.96 standard deviations away from the weighted mean failure rate for the high, medium, or low HCC group. Issuers with outlier failure rates in a particular HCC group will then have their sample enrollee risk scores adjusted by the difference between the issuer's failure rate and the mean failure rate for that HCC group for all applicable HCCs in their sample enrollees' risk scores. We will not use an overall mean failure rate or error rate to determine outliers under the approach finalized in this rule. We believe that the HCC grouping approach described above, which utilizes three large HCC groupings, will mitigate the risk of an issuer having a small sample size for a particular HCC group. We also note that we intend to propose updates to the sampling methodology for the 2018 benefit year HHS-operated risk adjustment data validation initial validation audit samples in the 2020 Payment Notice.

Comment: One commenter supported the proposed application of the difference between the calculated error rate and the statistically meaningful value, instead of the full error rate, to the issuer's subsequent year risk score when material deviation occurs. One commenter opposed the proposal due to concerns that if the average failure rate is exceedingly high or increasing, it could encourage issuers to be less accurate over time in their risk adjustment data, as long as they are not outliers relative to other issuers. Another commenter expressed concerns that issuers within the calculated confidence interval would receive no adjustments, while issuers outside of the confidence interval would receive substantial and punitive adjustments.

Response: The primary purpose of determining statistically meaningful differences is to avoid the unwarranted application of risk score adjustments—that is, risk scores would be adjusted only when the issuers' failure rates are outside a range of statistically acceptable errors. We believe that statistically meaningful errors should be adjusted to the weighted mean failure rate of each HCC group. We are finalizing an approach under which, when an issuer's failure rate for its associated HCCs in one of the HCC groupings is statistically different than the mean for that grouping, HHS will adjust the sample enrollees' risk score component for that HCC group by the difference between the issuer's failure rate for the HCCs in that group and the weighted mean failure rate for the HCC group for all issuers that submitted initial validation audits. We will continue to evaluate this approach; however, we expect that as issuers and initial validation auditors gain additional experience performing risk adjustment data validation, HCC failure rates should improve and stabilize, rather than grow.

Comment: Several commenters recommended that HHS provide issuers with more transparency about the calculation of error rates, as well as benchmark national and State-level error rate data against which issuers could evaluate their performance relative to other issuers and in the context of this proposal. Two commenters suggested that HHS apply the proposed approach to the 2016 benefit year pilot results to illustrate how issuers' risk scores and payment transfers might be affected in future years.

Response: We appreciate the recommendations, and we intend to publish benchmark failure and error rate data based on the results of the 2016 benefit year data validation second pilot year. We also intend to provide additional information to issuers about risk score error rates based on 2016 benefit year risk adjustment data validation results, prior to implementation in 2017 benefit year risk adjustment data validation. In addition, illustrations of the methodology we will use to evaluate failure rate differences by HCC group, calculate error rates based on failure rates and apply error rates to risk scores are provided above.

Comment: Two commenters recommended that HHS continue to study failure rates by HCCs or groups of HCCs for a longer period of time before proceeding with this approach, and another commenter opposed the calculation of failure rates at the HCC or HCC group-level.

Response: We evaluated the HCC group-level and other proposed approaches using a simulation with underlying Medicare risk adjustment data validation failure rates, and we agree with commenters that additional data from HHS-operated risk adjustment data validation results in a payment adjustment year would be preferable. However, under the current error rate estimation and application policy for HHS-operated risk adjustment data

[23] See section III.B.2.g.ii. of this rule, for a discussion of changes being finalized with respect to payment adjustments for issuers that have exited the market.

validation, all issuers' risk scores and payment transfers would be adjusted, for any identified error, regardless of issuer size or distribution of HCCs in its enrollee population beginning with the 2017 benefit year data validation. We believe the approach being finalized in this rule will increase predictability of risk adjustment transfers for issuers, and improve our ability to identify statistically meaningful data discrepancies in the data validation process. By focusing on issuer errors that are statistically meaningful, we can adjust issuers' risk scores with confidence, as opposed to adjusting all issuers for any difference, significant or not, from EDGE data. As such, we believe implementing this approach as soon as possible ensures the most accurate payment adjustments and promotes stability and predictability of risk adjustment transfers.

Comment: A few commenters raised concerns that the calculation of a national average error rate could fail to account for State or regional variations in provider coding practices, and therefore result in harmful adjustments that could discourage new entrants in some States.

Response: We agree with commenters and believe the evaluation of failure rate deviation by groups of HCCs, based on HCC failure rates outlined above, rather than a single, national average failure rate for all HCCs, will mitigate the risk of adjustments due to errors or differences that can be explained by regional variation in provider documentation of enrollee health status. We will evaluate the impact of this approach on issuers across regions and States and consider adjustments in future years if there is evidence of regional bias in payment adjustments resulting from this policy.

Comment: One commenter requested that HHS conduct another pilot year prior to implementing payment adjustments, since data validation is still new for issuers in the commercial market.

Response: While we will continue to educate issuers about the HHS risk adjustment data validation process, we believe that it is necessary to use the results of data validation to adjust risk scores beginning with 2017 benefit year data validation to encourage issuers to continue to improve the accuracy of data used to compile risk scores and to preserve confidence in the HHS-operated risk adjustment program.

ii. Payment Adjustments for Issuers That Have Exited the Market

In the 2015 Payment Notice, we established that HHS will use a prospective approach to adjust risk scores and payment transfers based on the results of risk adjustment data validation. Specifically, HHS will apply the error rate calculated through the risk adjustment data validation process for the applicable benefit year to plan risk scores in the subsequent benefit year, and then make risk adjustment payment transfers based on adjusted plan average risk scores in that subsequent benefit year. However, in some cases, an issuer of a risk adjustment covered plan may have exited a State market during or at the end of the benefit year being audited and therefore would not have risk scores or payment transfers in the subsequent benefit year to which HHS could make adjustments.

As previously noted, the purpose of risk adjustment data validation is to promote confidence in the budget-neutral payment transfer methodology by ensuring the integrity and quality of data provided from issuers. HHS believes that the prospect of not receiving payment adjustments based on the results of risk adjustment data validation results could undermine these goals by eliminating the incentive for an exiting issuer to carefully and accurately submit risk adjustment data for its final benefit year in the market. Not only could this type of inaccuracy result in overpayments to the exiting issuer, it could also cause the other issuers in the market to be over or undercompensated for the actual risk of their enrollee populations. Therefore, we proposed that HHS would use the error rate derived from the risk adjustment data validation process to adjust the payment transfer for the issuer's final benefit year in the State market, which would be concurrent with the benefit year being audited, for issuers that exit a State market during or at the end of the benefit year being audited. Because risk adjustment transfers for a given benefit year are calculated and paid before the risk adjustment data validation process for that benefit year is completed, this approach would require HHS to make a retroactive (that is, post-transfer) adjustment to the issuer's payment transfer for its final benefit year and reallocate the adjusted transfer amount to the other issuers in the State market in that year.

We sought comment on this proposal to make these adjustments to payment transfers for issuers that have exited the market based on the results of risk adjustment data validation for the most recent benefit year in which they participated in risk adjustment. We are finalizing this policy as proposed, and we clarify that it will be effective beginning with the 2017 benefit year risk adjustment data validation. Therefore, for an issuer that exited a State market during or at the end of the 2017 benefit year who had a statistically meaningful error rate under the revised approach to payment adjustments finalized above in this rule, HHS would apply the risk score error rate to the issuer's 2017 benefit year risk score, and recalculate 2017 benefit year risk adjustment transfers for the affected State market risk pools. We note that, under this timeline, issuers that exited a State market during or at the end of 2017 benefit year have ample opportunity to review and correct data submitted to their EDGE servers that will be used to calculate risk scores for the 2017 benefit year.

Comment: The majority of commenters supported using the error rate derived from data validation for the most recent benefit year in which an exited issuer participated in risk adjustment to make an adjustment to exited issuers' risk adjustment transfers for their final benefit year in the State market, and to reallocate the adjusted amount to the other issuers in the State market in that year. Commenters agreed that a post-transfer adjustment, based on results of data validation for the most recent benefit year for which the issuer participated in risk adjustment, would reduce the risk of gaming by an issuer leaving a State market and ensure that other issuers remaining in the State market are not harmed by an exited issuer's incorrect or incomplete data. One commenter expressed concern that the adjustments for exited issuers would complicate payment transfers and requested that HHS provide additional guidance or create a forum with issuers to discuss which method would result in the least disruption to the data validation process over multiple years.

Response: We agree with commenters who supported a post-transfer adjustment for issuers who exit the market during or at the end of a given benefit year, and we are finalizing the policy as proposed. Adjusting an exited issuer's payment transfer will help ensure that an issuer with inaccurate or incomplete data does not benefit from this error and that other issuers in the State market are not harmed by it. We acknowledge that adjustments to final benefit year payment transfers for issuers that exited a State market could complicate the calculation of transfers; however, we believe the revised policy for error rate payment adjustments finalized above will help mitigate the potential complexity, because only exited issuers with statistically meaningful failure rates will receive

post-transfer adjustments. Furthermore, we believe the benefits associated with applying adjustments to exited issuers' payment transfers, based on the results of risk adjustment data validation for the most recent benefit year in which they participated in risk adjustment, outweigh the complexities. For State market risk pools where HHS determines that an issuer that exited the market will receive an adjustment to their risk adjustment transfer for their final benefit year in the market, we intend to provide all issuers in the affected prior year risk pool with the adjustments for exited issuers at the same time as adjustments for any issuers remaining in the market are made in the subsequent benefit year.

iii. 500 Billable Member Months

Numerous small issuers have expressed concern regarding the regulatory burden and cost associated with complying with the risk adjustment data validation program. HHS has previously considered these concerns and provided relief where possible. In the proposed rule, we proposed that, beginning with 2017 benefit year risk adjustment data validation, issuers with 500 billable member months or fewer that elect to establish and submit data to an EDGE server would not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. We explained that we believe exempting issuers with 500 billable member months or fewer from the requirement to hire an initial validation auditor is appropriate because issuers of this size would have a disproportionately high operational burden for compliance with risk adjustment data validation. We noted that, beginning with 2018 benefit year risk adjustment data validation, these issuers would not be subject to random sampling under the materiality threshold discussed below, and would continue to not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. We also explained that if the approach for payment adjustments for error rates outlined in the proposed rule were finalized, then it would be possible that no adjustment would occur for issuers below this threshold. We sought comments on the proposal, including the 500 billable member month threshold.

We are finalizing the exemption for issuers with 500 billable member months or fewer as proposed. We clarify that, consistent with the approach in the 2017 Payment Notice for the lower, separate risk adjustment default charge for small issuers, the determination of whether an issuer has 500 billable member months or fewer will be calculated Statewide (that is, combining an issuer's enrollment in a State's individual and small group markets in a benefit year).

Comment: A commenter agreed with the proposal, but suggested that issuers with 500 or fewer billable member months be excluded from risk adjustment data validation entirely. One commenter disagreed with the proposal stating that all issuers should be subject to audits for accountability. One commenter agreed with the proposal, but wanted an option for small issuers to be adjusted by a default error rate based on the issuer's parent company's aggregate or average error rate.

Response: HHS recognizes that issuers' company-level affiliations may vary in size considerably, but note that regardless of parent company size, issuers with 500 or fewer billable member months Statewide face a relatively large burden in complying with an initial validation audit where the initial validation audit sample would be the issuer's entire population. Consistent with the risk adjustment data validation error rate payment adjustment policy finalized above, we believe that only issuers with statistically meaningful errors should receive payment adjustments. We believe that the implementation of this policy provides similar relief to smaller issuers for whom audits would have a disproportionately high cost and who, due to small size, are unlikely to have a significant or material impact on adjustments to other issuers. We note that the risk adjustment data validation policies finalized in this rule result in issuers with 500 or fewer billable member months Statewide effectively being excluded from risk adjustment data validation, as they do not have to hire an initial validation auditor, submit initial validation audit results, or be subject to risk adjustment data validation payment adjustments.

iv. Materiality Threshold for Risk Adjustment Data Validation

In the 2018 Payment Notice, HHS implemented a materiality threshold for risk adjustment data validation to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans. Specifically, we stated that issuers with total annual premiums at or below $15 million (calculated based on the premiums of the benefit year being validated) would not be subject to *annual* initial validation audit requirements, beginning with the 2017 benefit year, but would still be subject to an initial validation audit approximately every 3 years. HHS based the timeline for enforcement of the materiality threshold on the expectation that we would begin making payment adjustments based on the results of the 2016 benefit year risk adjustment data validation, effectively requiring all issuers of risk adjustment covered plans to participate in the first benefit year for which risk adjustment payments are adjusted. However, in light of our subsequent decision to convert the 2016 benefit year to another pilot year,[24] in the proposed rule, we proposed to postpone application of the materiality threshold to the 2018 benefit year. Therefore, all issuers of risk adjustment covered plans would be required to conduct an initial validation audit for the 2017 benefit year risk adjustment data validation, other than issuers with 500 billable member months or fewer Statewide as discussed above. Beginning with the 2018 benefit year risk adjustment data validation, issuers below the $15 million premium materiality threshold would not be required to conduct an initial validation audit every year. Under this proposal, HHS would still conduct random and targeted sampling under which issuers below the materiality threshold would be subject to an initial validation audit approximately every 3 years, beginning with 2018 benefit year risk adjustment data validation.[25] In addition, we explained that if the proposed approach for error rate payment adjustments outlined in the proposed rule were to be finalized, issuers below the $15 million threshold that are not selected for the random and targeted sampling might not have their risk adjustment transfers adjusted for a given benefit year.

We are finalizing the postponement of the materiality threshold to 2018 benefit year risk adjustment data validation, as proposed.

Comment: One commenter agreed with the proposal. Another commenter advocated for having a lower materiality threshold such as 12,000 or fewer billable member months. Some commenters stated that there should be no materiality threshold, and that all issuers should be subject to risk adjustment data validation.

[24] ''HHS-Operated Risk Adjustment Data Validation (HHS–RADV)—2016 Benefit Year Implementation and Enforcement.'' May 3, 2017. Available at *https://www.regtap.info/uploads/library/HRADV_PilotGuidance_5CR_050317.pdf.*

[25] In the 2018 Payment Notice, we stated that we would consider risk-based metrics such as an issuer's prior year risk adjustment data validation results and material changes to data submission, as measured by our quality metrics, in selecting issuers below the materiality threshold for more frequent initial validation audits.

Response: Although we appreciate the comments, we did not propose and are not modifying the level at which the materiality threshold is set in this rule. The proposal addresses the timing for implementation of the threshold and the applicability of potential adjustments to risk adjustment transfers for issuers at or below the $15 million threshold. All issuers of risk adjustment covered plans will be required to conduct an initial validation audit for the 2017 benefit year risk adjustment data validation, other than issuers with 500 billable member months or fewer Statewide as discussed above. Beginning with the 2018 benefit year, issuers at or below the $15 million premium threshold will not be required to conduct an initial validation audit every year. HHS will still conduct random and targeted sampling under which issuers below the materiality threshold would be subject to an initial validation audit approximately every 3 years, beginning with 2018 benefit year risk adjustment data validation. Under the policy finalized in this rule with respect to error rate payment adjustments, issuers below the $15 million materiality threshold that are not selected for the random and targeted sampling will not have their risk adjustment transfers adjusted.

v. Data Validation Sampling Methodology

Section 153.350(a) requires that a statistically valid sample of enrollees from each issuer of risk adjustment covered plans be validated. In the 2015 Payment Notice, HHS finalized its methodology for selecting the sample of enrollees for the initial validation audit for each issuer of a risk adjustment covered plan. We established a sample size per issuer for each State in which the issuer offers risk adjustment covered plans.[26] In the proposed rule, we explained that HHS would not calculate a risk score, or apply risk adjustment payment transfers except for high-cost risk pool transfers beginning with the 2018 benefit year, on behalf of a State in a market and risk pool when there is only one issuer in the market and risk pool. In addition, we proposed that the issuer would not be required to validate data for its plans in a risk pool that was not risk adjusted against another issuer in the State risk pool in the applicable benefit year. Therefore, we proposed to change the sampling methodology so that, beginning with the 2017 benefit year data validation, the initial data validation audit sample would only include enrollees from State risk pools in which there was more than one issuer.[27] We are finalizing this policy as proposed.

Comment: One commenter stated that the proposed approach to allow sole issuers to participate in another market in the State where it is not the sole issuer has the potential to create market instability, as non-similar plans are brought into the calculation.

Response: We clarify that, under the finalized policy, HHS would only sample from the issuer's risk pool where it is not the only issuer in the risk pool for the initial validation audit. Currently, the initial validation audit sample pulls from an issuer's population across a State, irrespective of risk pool. The finalized policy ensures that only enrollee data for which risk adjustment transfers were calculated in a risk pool are validated.

Comment: One commenter disagreed with our proposal due to concerns about accountability of sole issuers.

Response: For issuers that are the sole issuer in a risk pool, there is no risk adjustment transfer and thus, there is no payment or accountability to other issuers in that risk pool. As explained above, HHS will not calculate a risk score or risk adjustment payment transfers, on behalf of a State in a market and risk pool in which there is only one issuer, except for high-cost risk pool transfers beginning with the 2018 benefit year, and data submitted for high-cost risk pool transfers by all issuers will be subject to a separate audit. Therefore, we are finalizing the proposal to change the sampling methodology so that, beginning with 2017 benefit year risk adjustment data validation, the initial validation audit sample will only include enrollees from State risk pools in which there was more than one issuer and where HHS conducted risk adjustment on behalf of the State for the benefit year being validated.

vi. Mental and Behavioral Health Records

Under § 153.630(b)(6), the issuer of a risk adjustment covered plan must provide the initial validation auditor and second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission. Issuers have advised HHS that certain States' medical privacy laws may limit providers' ability to furnish mental and behavioral health records for risk adjustment data validation purposes. As we explained in the proposed rule, we believe that section 1343 of the PPACA and associated regulations require issuers of risk adjustment covered plans to furnish any records needed for purposes of the risk adjustment program, including mental and behavioral health records, and that the HIPAA Privacy Rule at 45 CFR 164.512(a) generally permits disclosures of protected health information that are required by law within the meaning of § 164.103. Nevertheless, we recognize that some State and Federal privacy laws impose requirements for mental and behavioral health information that are different from, and potentially more restrictive than, the HIPAA regulations. However, without the necessary mental and behavioral health information, the diagnosis code for an applicable enrollee cannot be validated and, therefore, it would be rejected during risk adjustment data validation.

To address these potential issues, we proposed to amend § 153.630(b)(6) to provide that, if a provider is prohibited from furnishing a full mental or behavioral health record by State or Federal privacy laws, the provider instead may furnish a mental or behavioral health assessment that providers routinely prepare, for validation of a mental or behavioral health diagnosis. We explained that, although HHS needs the full content of the mental or behavioral health record to ensure full validation of the accuracy of diagnosis codes, we believed that we can still perform some risk adjustment data validation based on the information contained in mental or behavioral health assessments in those instances in which State or Federal law prohibits submission of the full record. For risk adjustment data validation purposes, we would expect a mental or behavioral health assessment to be signed by a qualified provider who is licensed by the State to diagnose mental illness and, to the extent permissible under governing privacy and confidentiality laws, to contain: (i) The enrollee's name; (ii) sex;[28] (iii) date of birth; (iv) current

[26] The proposed rule described the sampling methodology incorrectly by stating that the sample would include 200 enrollees per issuer for each risk pool in which the issuer participates, instead of 200 enrollees per issuer across risk pools.

[27] For the 2018 and future benefit years, HHS would not require the sole issuer in the State market risk pool to include high-cost risk pool enrollees in its sample for data validation, as these payments will be subject to a separate audit process.

[28] For purposes of consistency, we made a technical revision to the name of this data element to ''sex'' in the final rule, rather than ''gender'' as

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status of all mental or behavioral health diagnoses; and (v) dates of service. We noted that ''psychotherapy notes,'' a subset of mental and behavioral health information that receives special protections under the HIPAA Privacy Rule, are not required for the purposes of risk adjustment data validation.[29] We also noted that some State and Federal privacy laws require that providers obtain patient consent before disclosing mental or behavioral health records, and that these consent requirements may apply to mental or behavioral health assessments. We clarified that we do not view a State or Federal law requiring patient consent as inconsistent with the risk adjustment data validation requirements to furnish a mental or behavioral health record or assessment. Additionally, we noted that certain substance use disorder patient records are subject to the Federal confidentiality law at 42 U.S.C. 290dd–2 and the regulations issued thereunder in 42 CFR part 2 and certain State laws, and generally require consent prior to disclosure. We stated that we believed that this proposal is consistent with the foregoing Federal and State confidentiality rules, and that the substance use disorder confidentiality requirements should govern when applicable. Therefore, issuers or providers may be required to obtain written patient consent to comply with this proposal.

We noted the proposal would allow issuers an additional avenue to achieve compliance by permitting abbreviated mental or behavioral health assessments for risk adjustment data validation in the event that a provider is subject to State or Federal privacy laws that prohibit the provider from providing a complete mental or behavioral health record to HHS. Under the proposal, to submit a mental or behavioral health assessment instead of the full mental or behavioral health record, a provider would be required to attest that relevant State or Federal privacy laws prohibit him or her from providing the complete mental or behavioral health record. We explained in the proposed rule that we also believed that the proposal supports the integrity of the risk adjustment data validation program by ensuring that an initial validation auditor obtains data that will enable proper validation of mental or behavioral health HCCs, which are susceptible to discretionary coding. Furthermore, we noted our belief that the flexibility to use mental or behavioral health assessments would minimize the burden on providers of complying with this requirement because providers may be able to utilize records they routinely prepare and may already have, as opposed to preparing special summaries solely for the purpose of risk adjustment data validation.

Based on our review of the comments we received, we are generally finalizing the amendments to § 153.630(b)(6) to permit providers that are prohibited by State law from furnishing a full mental or behavioral health record to submit an assessment instead. We are making one clarification to convey that this flexibility will not apply to providers that are prohibited solely by Federal law from furnishing a full mental or behavioral health record. We recognize that other State and Federal laws, including the Federal confidentiality law at 42 U.S.C. 290dd–2 and associated regulations that govern certain patient substance use disorder records potentially apply to mental or behavioral health assessments, and would require a provider to obtain enrollee consent before disclosing the assessment if applicable. We reiterate that the proposal on mental or behavioral health assessments was not intended to provide an exception to any applicable enrollee consent requirement under State or Federal law.

Comment: Most commenters supported the proposal. These commenters stated that the proposal would reduce burden, ensure compliance with privacy rules, and assist with the chart retrieval process. Others supported the proposal with certain modifications. For example, one commenter requested a safe harbor if mental health diagnosis failure, or error rates, are high due to noncompliance from mental health providers. Similarly, another commenter requested that HHS avoid punitive payment adjustments for issuers whose production of records is constrained by compliance with State law. The commenter also requested that HHS acknowledge the existence of varying State-specific limitations on consent for disclosure of mental or behavioral health records, evaluate the extent to which State-specific rules can be appropriately incorporated into the data collection, and engage in a separate solicitation of input from stakeholders on this topic.

Response: Since we only have final results from the first pilot year of risk adjustment data validation thus far, we do not currently have adequate experience to be able to determine whether failure rates for mental health diagnoses are higher than other diagnoses, and whether those failure rates are consistent by State. The policy for error rate payment adjustments finalized in this rule mitigates the potential for punitive payment adjustments, because only issuers with statistically meaningful failure rates will receive risk score error rates resulting in payment transfer adjustments.[30] We will continue to evaluate whether additional relief is necessary, based on analysis of risk adjustment data validation results. Our policy to permit the use of mental or behavioral health assessments by providers that are prohibited by State law from furnishing a full record is intended to offer broadly applicable relief and flexibility to account for the variation in privacy laws in particular States. Therefore, we do not intend to solicit input on or otherwise engage in an evaluation of State-specific requirements.

Comment: Two commenters expressed concern that initial validation auditors may interpret or utilize mental or behavioral health assessments differently, and requested that HHS provide guidance or training to ensure consistent interpretation of the assessments.

Response: We agree that consistent interpretation and utilization of mental and behavioral health assessments is important, and seek to encourage it. For purposes of risk adjustment data validation, the assessment is limited to the five discrete elements specified in § 153.630(b)(6), most of which are straightforward, so HHS does not anticipate a material risk of disparate interpretation or utilization of mental or behavioral health assessments by initial validation auditors. HHS continues to work to leverage existing provider networks and communication channels to educate providers on the HHS-operated risk adjustment data validation requirements.

Comment: One commenter requested the extension of flexibility to the actual submission of documentation regarding treatment for mental or behavioral health conditions, expressing concern that there may not be an affected

was specified in the proposed rule. HHS uses the data element of sex, as biologically determined, to calculate enrollees' risk scores under the PPACA risk adjustment program.

[29] ''Psychotherapy notes'' are notes recorded by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session, or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy notes do not include medication prescription and monitoring, counseling session start and stop times, modalities and frequency of treatment, test results, and summaries of diagnoses, functional status, treatment plan, symptoms, prognosis, and progress to date. See § 164.501.

[30] Please see the above preamble section on ''Payment Adjustments for Error Rates'' for more information.

underlying record to identify in the first instance. The commenter also requested additional information regarding who bears responsibility for preparation of the mental or behavioral health assessment and how it differs from a full record.

Response: The provider is responsible for preparing the mental or behavioral health assessment, and the assessment is limited to the five elements specified in § 153.630(b)(6). When being used for risk adjustment data validation purposes, it should be accompanied by the provider's signature and an attestation that State privacy laws prohibit the provider from furnishing a complete medical record. This policy provides flexibility in cases where the State law prevents submission of the full record, but that flexibility does not extend to the provision of any documentation regarding mental or behavioral health conditions. HCCs without adequate documentation, whether through a full record or a mental or behavioral health assessment, would result in an error.

Comment: Several commenters did not support the proposal. For example, one commenter indicated that this policy of permitting mental or behavioral health assessments would not significantly reduce burden, and generally objected to the other State or Federal laws that may require the provider to obtain patient consent, indicating that doing so may not be possible. One commenter stated that requiring provider attestation or patient consent will add burden and reduce the likelihood of mental or behavioral health records being furnished by issuers in risk adjustment data validation. The commenter also expressed concern that there will likely be higher error rates for HCCs related to mental health or substance use disorders.

Response: HHS believes that the finalized policy to permit the use of existing mental or behavioral health assessments affords flexibility to providers to use an alternative source for the documentation that otherwise would be necessary under risk adjustment data validation to maintain the integrity of the risk adjustment program while complying with State and Federal privacy requirements. As discussed previously in this section and in the proposed rule, State and Federal privacy requirements may independently require a provider to obtain patient consent in order to furnish a mental or behavioral health assessment. In providing the flexibility to submit assessments for risk adjustment data validation purposes, HHS does not intend to limit or otherwise affect the application of any such consent requirements under State or Federal law, which provide important protections to enrollees.

HHS recognizes, however, that our policy to allow providers to furnish a mental or behavioral health assessment may impose a slight increase in the burden of compliance with risk adjustment data validation requirements because the assessment must be accompanied by an attestation from the provider. Attestations are necessary to demonstrate that the provider is prohibited from furnishing the complete medical record by State privacy laws, but we do not expect compliance with the attestation requirement to be difficult.

As noted above, HHS does not intend to exempt providers from any other applicable consent requirements under State or Federal law, and we do not yet have adequate experience as to whether failure rates will be higher for mental health conditions or substance use disorders. We reiterate that only issuers with statistically meaningful failure rates will receive risk score error rates and subsequent payment transfer adjustments pursuant to the policy finalized in this rule.[31] We will analyze risk adjustment data validation results to evaluate the impact of this policy on error rates, and will consider whether further refinements are appropriate.

Comment: Commenters expressed concern that enrollees could be waiving their HIPAA rights if their providers furnish medical records that include enrollees' diagnoses for risk adjustment data validation. The commenter suggested that if a diagnosis can be imputed by the presence of a prescription drug, HHS should include treatments for mental illness as a drug class in the risk adjustment models, to impute diagnoses for which a medical record cannot easily be obtained.

Response: As noted above and in the proposed rule, we believe that section 1343 of the PPACA and associated regulations require issuers of risk adjustment covered plans to furnish any records needed for purposes of the risk adjustment program, including mental and behavioral health records. The HIPAA Privacy Rule generally permits disclosures that are required by law (see 45 CFR 164.512(a)). We recognize that some State and Federal privacy laws impose requirements for mental and behavioral health information that are different from, and potentially more restrictive than, the HIPAA regulations, and may require that providers obtain patient consent before disclosing mental or behavioral health records or assessments. We do not view the risk adjustment data validation requirements to furnish a mental or behavioral health record or assessment as inconsistent with these consent requirements or involving any ''waiver'' of enrollee privacy rights.

As discussed in the 2018 Payment Notice, in specific instances, risk adjustment permits the use of prescription drugs to impute diagnoses. As noted elsewhere in this rule, HHS will continue to evaluate the inclusion of additional prescription drug classes in the risk adjustment model, including mental or behavioral health treatments, to potentially impute missing diagnoses for future benefit years.

Comment: One commenter requested that HHS provide issuers flexibility to develop standard language requiring the provider's signature to ease the administrative burden of creating mental or behavioral health assessments.

Response: The approach being finalized in this rule does not prevent an issuer from developing standard language for the provider attestation if the issuer believes it will help providers furnish mental or behavioral health assessments and other required documentation for risk adjustment data validation purposes.

Comment: Some commenters expressed concerns about the Federal rules governing confidentiality of substance use disorder patient records under 42 CFR part 2, or their alignment with the HIPAA Privacy Rule.

Response: The comments on the Federal rules governing confidentiality of substance use disorder patient records under 42 CFR part 2 and the HIPAA Privacy Rule concern regulations that are implemented and enforced by other agencies within HHS, the Substance Abuse and Mental Health Services Administration and the Office for Civil Rights, respectively. Although we appreciate these comments, we are not able to address them in this rulemaking.

vii. Inter-Rater Reliability Rates

Under § 153.630(b)(8), the initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. An initial validation auditor must achieve a consistency measure of at least 95 percent for his or her review outcomes, except for the initial benefit years of risk

[31] Please see the above preamble section on ''Payment Adjustments for Error Rates'' for more information.

adjustment data validation, for which the initial validation auditor may meet an inter-rater reliability standard of 85 percent. Consistent with our decision to make the 2016 benefit year another pilot year as referenced above, we proposed to amend § 153.630(b)(8) to add the 2016 benefit year as an initial year of risk adjustment data validation for which the initial validation auditor may meet the lower inter-rater reliability standard of 85 percent. We are finalizing the amendment to § 153.630(b)(8) as proposed.

Comment: All commenters supported the addition of the 2016 benefit year as an initial year of risk adjustment data validation for which the initial validation auditor may meet an inter-rater reliability standard of 85 percent. One commenter noted that permitting the 85 percent standard for another year would allow issuers to gain an additional year of experience and process improvement before the standard is increased.

Response: We agree with commenters and are finalizing the amendment to § 153.630(b)(8) as proposed.

viii. Civil Money Penalties

An effective risk adjustment data validation program is essential to the proper functioning of the HHS-operated risk adjustment program. In order to enforce risk adjustment data validation standards when operating risk adjustment data validation on behalf of a State, we proposed to clarify and amend the bases upon which HHS may impose CMPs for violations of risk adjustment data validation requirements.

To give HHS additional flexibility for ensuring compliance with the risk adjustment data validation requirements and in light of our experience in the first pilot year of the risk adjustment data validation program, HHS proposed to amend § 153.630(b)(9) to give HHS the authority to impose a CMP on an issuer of a risk adjustment covered plan in the event of misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements. Specifically, we proposed to amend § 153.630(b)(9) to state that, if an issuer of a risk adjustment covered plan (1) fails to engage an initial validation auditor; (2) fails to submit the results of an initial validation audit to HHS; (3) engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or (4) intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS, HHS may impose CMPs in accordance with the procedures set forth in § 156.805(b) through (e). We note that § 153.630(b)(9) already addresses the possible imposition of CMPs for (1) and (2) above, and provides a cross-reference to § 156.805, which contains the bases and procedures for imposing CMPs for (3) and (4) above. Section 153.630(b)(9) provides the authority to assess CMPs on all issuers of risk adjustment covered plans, not just issuers on an FFE as does § 156.805.[32] We clarified that the proposal to impose CMPs for (3) and (4) would apply to all issuers of risk adjustment covered plans, not just those issuers on an FFE. We noted that the CMP authority would be in addition to HHS's ability to adjust an issuer's transfers under § 153.350(c).

As previously noted in the Second 2013 Program Integrity Rule, and in the 2015 Payment Notice, we proposed that HHS's possible application of CMPs would continue to take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record of non-compliance (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances. Additionally, we would continue to impose any CMPs so that the level of the enforcement action is proportional to the level of the violation. While we reserved the right to impose penalties up to the maximum amounts set forth in § 156.805(c), as a general principle, we explained that we intend to work collaboratively with issuers to address any problems in conducting the risk adjustment data validation process.

We believe this additional CMP authority will improve program integrity and fairness by permitting HHS the authority to assess CMPs on issuers that engage in misconduct in risk adjustment data validation. Although § 153.630(e) permits HHS to adjust payments and charges for issuers that do not comply with audit requirements and standards, this provision only makes the markets whole in the event of a violation of the risk adjustment data validation standards or misconduct. We do not believe this provision provides a sufficient deterrent effect to ensure program integrity of the risk adjustment data validation program. Additionally, we believe this additional authority is necessary in light of the policies finalized in the 2018 Payment Notice, specifically, the concerns HHS highlighted around gaming and the inclusion of prescription drug data in the risk adjustment model. We are finalizing as proposed the amendments to § 153.630(b)(9) to clarify and strengthen HHS's CMP authority. We also clarify that HHS would not impose a CMP under § 153.630(b)(9) for a benefit year on an issuer that is not required to submit an initial validation audit for risk adjustment data validation for that benefit year.

Comment: Most of the comments received supported the proposal. One commenter requested definitions for misconduct, substantial noncompliance, and reckless misrepresentation, along with examples for each case under which an issuer could receive a CMP.

Response: The terms misconduct, substantial noncompliance, and reckless misrepresentation are incorporated from § 156.805(a)(1) and (5). Examples of issuer misconduct that could warrant imposition of a CMP under the amended § 153.630(b)(9) include knowingly hiring an initial validation auditor who has conflicts of interest, or failing to ensure confidentiality and security of data transmitted to the initial validation auditor or second validation auditors. Examples of substantial noncompliance include unreasonable delays in providing complete enrollment documentation, claims and encounter data, or medical records documentation to an auditor, or failing to properly oversee an initial validation auditor. However, the determination of whether conduct rises to the level of any of these terms in any specific case is highly fact sensitive, involving consideration of any mitigating or aggravating factors.

ix. Adjustment of Risk Adjustment Transfers Due to Submission of Incorrect Data

On September 2, 2015, HHS released the *Adjustment of Risk Adjustment Transfers Due to Submission of Incorrect Data* guidance,[33] describing the process by which HHS addresses instances of materially incorrect EDGE server data submissions. We reiterated this guidance on November 3, 2017, through the release of *Evaluation of EDGE Data Submissions for the 2017 Benefit Year.*[34] We proposed to include risk adjustment data validation as a

[32] Pursuant to § 153.20, *risk adjustment covered plan* means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in 45 CFR 146.145(c), individual health insurance coverage described in 45 CFR 148.220, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.

[33] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RA-Adjustment-Guidance-9-2-15.pdf.*

[34] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-Submissions-2017.pdf.*

method of discovering materially incorrect EDGE server data submissions and making adjustments pursuant to § 153.630(e), as described in the September 2, 2015 guidance.[35] We proposed that demographic or enrollment errors discovered during risk adjustment data validation would be the basis for an adjustment to the applicable benefit year transfer amount, rather than the subsequent benefit year risk score. The elements being validated are related to the transfer formula and demographic variables in the risk adjustment models. We explained that we believe the process of identifying demographic and enrollment errors is substantially similar to a discrepancy in the transfer formula, which is addressed in the current benefit year as part of the EDGE data discrepancy process under § 153.710, as opposed to a discrepancy in underlying enrollee diagnoses contributing to risk scores, which is addressed through subsequent year risk score adjustments as part of risk adjustment data validation.

An overstatement or understatement of premium data may affect issuers differently, because it will lead to an increase or decrease in the absolute value of the magnitude of the risk adjustment transfers (and will affect the calculation of the geographic rating area factors). Therefore, an issuer's submission of incorrect EDGE server premium data may have the effect of increasing or decreasing the magnitude of risk adjustment transfers to other issuers in the market, depending on the direction of the premium error, holding constant the other elements of the payment transfer formula. In cases where there is a material impact on risk adjustment transfers for that particular market as a result of incorrect EDGE server premium data, HHS would calculate the dollar value of differences in risk adjustment transfers, and, where the difference is detrimental to one or more issuers in the market, adjust the other issuers' risk adjustment transfer amount by that calculation, and increase the risk adjustment charge (or decrease the risk adjustment payment) to the issuer that made the data error, in order to balance the market.[36] We explained that we believe this approach would allow HHS to operate the risk adjustment program efficiently, while ensuring that issuers do not profit from their data submission errors or harm their competitors in the relevant market. We sought comment on this proposal.

We are finalizing this policy as proposed.

Comment: Commenters supported the proposal, or agreed with it but requested additional clarification. For example, one commenter requested examples of materially incorrect data submissions. Another commenter sought clarification on certain technical issues related to the proposal, including the definition of demographic and enrollment data errors, whether these errors will impact elements of the transfer formula, the error rate, or both, and the timing of any adjustments that HHS would make with respect to current year risk adjustment transfer amounts and related data transfer element errors. One commenter supported HHS's current approach of taking a subsample of 50 enrollees to verify demographic and enrollment information, but stressed that the subsample results should not be the sole basis for applying current year transfer adjustments. Rather, if errors are identified from the subsample, HHS should then investigate the issuer's data further to assess if there were materially incorrect EDGE data submissions.

Response: We clarify that significant errors found in the risk adjustment data validation demographic and enrollment subsample review will result in communications from HHS to the issuer regarding the issuer's underlying data before the potential application of any adjustments to risk adjustment transfers. The demographic and enrollment data elements collected for purposes of risk adjustment are date of birth, sex, plan identifier, enrollment start and end dates, premium amount, and rating area. In addition to the issues described above regarding incorrect premium, certain demographic or enrollment errors could indicate the presence of larger issues such as assignment of enrollees to the incorrect model or metal level, which would lead to incorrect risk scores and a miscalculation of the AVs and induced demand factors (IDF) in the transfer formula, or incorrect age factors. If this occurs, we would initiate a separate process outside of risk adjustment data validation to further evaluate the impact of the incorrect data submission, determine whether the market needs to be made whole due to the errors, and then make the necessary adjustments to affected issuers. Therefore, HHS will not be relying solely on subsample results as the basis for applying current year transfer adjustments. Whether an error has an effect on the transfer formula, error rate, or both amounts will depend on the specifics of the error. For example, if an error affects premiums alone, only the Statewide average premium would need to be adjusted. HHS intends to be in communication with affected issuers throughout the second validation audit process, and to resolve potential discrepancies in a manner similar to the EDGE data submission discrepancy process.

h. Risk Adjustment User Fee for the 2019 Benefit Year (§ 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 its behalf. In 2019, HHS will be operating a risk adjustment program in every State. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the per member per month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

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

In the 2018 Payment Notice, we calculated the Federal administrative expenses of operating the risk adjustment program for the 2018 benefit year to result in a risk adjustment user fee rate of $1.68 per billable member per year or $0.14 PMPM, based on our estimated contract costs for risk adjustment operations and estimates of billable member months for individuals enrolled in a risk adjustment covered plan. For the 2019 benefit year, we proposed to use the same methodology to estimate our administrative expenses to operate the program. These contract costs cover development of the model

[35] This guidance is also included in the *Evaluation of EDGE Data Submissions for the 2017 Benefit Year,* released on November 3, 2017, available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-Submissions-2017.pdf.*

[36] Calculation of the dollar value will include adjustment to the Statewide premium average and, to the extent possible, adjustment to the geographic cost factor.

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 in HHS-operated risk adjustment States for the benefit year.

We previously estimated that the total cost for HHS to operate the risk adjustment program on behalf of States for 2019 will be approximately $38 million, and the risk adjustment user fee would be $1.68 per billable member per year, or $0.14 PMPM. However, we now estimate the cost for HHS to operate the risk adjustment program on behalf of States for the 2019 benefit year to be approximately $40 million, and are finalizing a risk adjustment user fee of $1.80 per billable member per year, or $0.15 PMPM, to take account of eligible administrative and personnel costs related to the operation of the HHS-operated risk adjustment program that were previously excluded from the estimate.

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

1. Applicability (§ 154.103)

Since July 18, 2011, issuers have been required to submit rate filing justifications for rate increases for non-grandfathered plans in the individual and small group markets. This requirement was established, in part, to carry out the Secretary's responsibility, in conjunction with States, under section 2794(b)(2)(A) of the PHS Act to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. Student health insurance coverage is considered by HHS to be a type of individual market coverage and is generally subject to the PHS Act individual market requirements, which has included rate review. We proposed to modify § 154.103(b) to exempt student health insurance coverage from the Federal rate review requirements, effective for plan or policy years beginning on or after January 1, 2019. As we discussed in the proposed rule, and as commenters noted, student health insurance coverage is generally rated and administered differently from other forms of individual health insurance coverage.[37]

States have allowed rating practices for student health insurance coverage to be more in line with large group pricing, in which experience rating and other factors can be used to determine rates. Because student health insurance coverage is typically experience rated, and is typically only available to students and their dependents with an open enrollment period coinciding with the start of the academic year, it is exempt from single risk pool rating requirements and not guaranteed to be available or renewable to individuals who are not students or dependents of students in an institution of higher education. We are finalizing the exemption as proposed, except that we are modifying the applicability date to align with the timing of when student health insurance coverage typically begins, such that the exemption will be effective for student health rate filings for the next plan year. This change, effective for student health insurance coverage effective on or after July 1, 2018, will reduce the regulatory burden on States and issuers of student health insurance plans.

Comment: Most commenters supported the proposal to exempt student health insurance coverage from Federal rate review requirements. Commenters suggested that the exemption should apply to coverage effective on or after July 1, 2018, to coincide with the traditional school year. Some commenters expressed concern that exempting student health insurance coverage would result in minimal oversight and decreased affordability.

Response: We are finalizing the exemption and it will apply to student health insurance coverage, as defined in § 147.145, with an effective date on or after July 1, 2018. We note that States maintain the flexibility to review rate increases of any size and any other aspects of student health insurance coverage. In States that do not have an Effective Rate Review Program, we will continue to monitor the compliance of student health insurance coverage with applicable market rating reforms based on complaints and as part of targeted market conduct examinations. In States where we are enforcing market reforms, we will continue to review form filings for student health insurance coverage for compliance with applicable PHS Act individual market requirements.

[37] *See* preamble discussion in the final rule, ''Health Insurance Market Rules; Rate Review'' 78 FR 13406, 13424 (February 27, 2013).

2. Rate Increases Subject to Review (§ 154.200)

Section 2794(a)(1) of the PHS Act requires the Secretary, in conjunction with States, to establish a process for the annual review of unreasonable premium increases for health insurance coverage. Section 2794(a)(2) of the PHS Act requires health insurance issuers to submit to the Secretary and relevant State a justification for an unreasonable premium increase prior to implementation. States may establish a more robust review process, and many have.

Section 154.200(a)(1) currently provides that a rate increase for single risk pool coverage beginning on or after January 1, 2017 is subject to a reasonableness review if: (1) The average increase, including premium rating factors described in § 147.102, for all enrollees, weighted by premium volume for any plan within the product, meets or exceeds 10 percent; or (2) the increase exceeds a State-specific threshold approved by the Secretary. We proposed to amend this provision to establish a 15 percent default threshold for reasonableness review, in recognition of significant rate increases in the past number of years, rather than the current 10 percent default threshold.[38]

Section 154.200(a)(2) currently requires States to submit a proposal to the Secretary for approval of any State-specific threshold. We proposed to amend § 154.200(a)(2) to require submission of a proposal only if the State-specific threshold is higher than the Federal default threshold. We proposed this change to reduce burden and promote State flexibility.

We also proposed to delete paragraph (b) in its entirety. That paragraph currently requires that the Secretary publish a notice each year indicating which threshold applies to each State. For States that request a State-specific threshold above what is set by CMS, CMS noted it would continue to post information on its website beginning with requests submitted on or after January 1, 2019.

We proposed to redesignate paragraph (c) as paragraph (b) and revise that paragraph to delete the language related

[38] The 10 percent threshold was established in the ''Rate Increase Disclosure and Review'' Final rule (76 FR 29963, May 23, 2011) based upon three indices. These indices are: (1) The medical component of the Consumer Price Index (CPI); (2) the National Health Expenditure data (NHE); and (3) the Standard and Poor's Healthcare Economic Commercial Index. The threshold was finalized at 10 percent based on the analysis of the trend in health care costs and rate increases provided in the preamble to the proposed rule.

to rates filed for coverage beginning before January 1, 2017, currently captured in paragraph (c)(1) as this provision is no longer necessary.[39] We proposed to redesignate paragraph (d) as paragraph (c). Finally, we proposed conforming changes to update the cross references in § 154.200 to align with the changes described above.

We are finalizing these changes as proposed with one modification, described below. These changes will apply to single risk pool rate filings submitted by issuers for plan or policy years beginning on or after January 1, 2019.

Comment: Some commenters supported a threshold increase, noting that raising the threshold to 15 percent would allow regulators to focus their attention on higher rate increases and reduce the regulatory burden for both States and issuers. Other commenters supported raising the threshold, but did not specify an alternative to 10 percent. Many commenters opposed changing the reasonableness review threshold to 15 percent, concerned that the change may normalize excessive increases. Other commenters opposed the change because it would negatively affect transparency of rate setting, noting that the Consumer Justification Narrative (Part II of the Rate Filing Justification) is only required for increases that meet or exceed the review threshold. Some commenters suggested a 6 percent threshold would be appropriate because that would be in line with health expenditures and still above the general rate of inflation. A few commenters suggested there should be a 15 percent threshold at the product level and 20 percent threshold at the plan level.

Response: We note that the threshold set by HHS constitutes a minimum standard. By increasing the threshold trigger to 15 percent, we are providing an opportunity for States to reduce their review burden, although most States currently employ stricter rate review standards and may continue to do so. Additionally, increasing the Federal default threshold for review will reduce burden for issuers. After an analysis of all rates subject to review that were determined to be ''unreasonable'' since the inception of the review threshold, only one filing with this determination has fallen between the 10 to 15 percent range. For these reasons, we do not believe this change will normalize excessive increases.

We are not lowering the threshold to 6 percent, as doing so may increase the burden on issuers and States. We are not establishing two thresholds (one at the product level and one at the plan level). When determining whether an increase is subject to review, rate increases are calculated at the plan level. That ensures that a plan that experiences a significant rate increase does not avoid review simply because the average increase for the product did not meet or exceed the applicable threshold. Because consumers are affected by rate increases at the plan level, we believe that increases for the plan, not the product, should continue to be the trigger for determining whether an increase is subject to review.

We expect the change to have a minimal impact on transparency. All issuers must continue to submit a Uniform Rate Review Template (URRT) (Part I of the Rate Filing Justification) for all single risk pool plan submissions. Issuers offering a QHP or any single risk pool submission containing a rate increase of any size must continue to submit an actuarial memorandum (Part III of the Rate Filing Justification). We are finalizing the proposal to change the Federal default review threshold to 15 percent beginning with single risk pool rate filings submitted by issuers for plan or policy years beginning on or after January 1, 2019.

Comment: Some commenters opposed CMS requiring submission of a proposal (and posting of that proposal) only if the State-specific threshold is higher than the Federal default threshold.

Response: The Federal review threshold is a minimum standard. States are able to apply a stricter standard, and many already do. Because States that apply a lower threshold meet the Federal minimum standard, we do not believe it is necessary or appropriate to require those States to submit a proposal to CMS. Therefore, we are finalizing the proposed changes to § 154.200(a)(2) with the following modification: We added language to clarify that these State proposals must be submitted in the form and manner specified by the Secretary. CMS will only require a proposal from States requesting a higher threshold. States that impose stricter standards will communicate those standards to their issuers as they currently do with many other aspects of State-specific requirements. CMS will post information from States that request a threshold higher than 15 percent and will issue further guidance on the process for submission and review of such State requests.

3. Submission of Rate Filing Justification (§ 154.215)

Section 154.215(h)(2) includes a reference to 45 CFR 5.65, which defined trade secret and confidential commercial or financial information under HHS regulations implementing the Freedom of Information Act, 5 U.S.C. 552. HHS revised 45 CFR part 5 in a final rule issued on October 28, 2016, effective on November 28, 2016 (81 FR 74930). We proposed to make a technical correction to § 154.215(h)(2) to refer to 45 CFR 5.31(d) because 45 CFR 5.65 no longer exists and § 5.31(d) now lists the reasons a record may be withheld. We are finalizing the change as proposed.

Comment: Some commenters opposed CMS's use of the Freedom of Information Act and requested issuer information be provided without any redaction.

Response: We proposed and are finalizing a technical correction to the regulatory reference. We did not propose any change to our interpretation of a trade secret and confidential commercial or financial information. The issuer may submit a redacted actuarial memorandum, but CMS does not make any redaction beyond what is submitted in the rate filing.

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

Section 154.220(b) provides that a health insurance issuer must submit applicable sections of the Rate Filing Justification for all single risk pool coverage in the individual or small group market by the earlier of (1) the date by which the State requires submission of a rate filing; or (2) the date specified in guidance by the Secretary. We have interpreted that section to require submission of all rate filings, for both QHPs and non-QHPs, at a uniform time.[40] We proposed to allow a State to set a later submission deadline for issuers who offer non-QHPs only, starting with the 2019 plan year. We are finalizing the change as proposed.

Comment: Some commenters expressed concern that the proposal provides an advantage to issuers offering only non-QHPs and may provide an opportunity for competitors to shadow price. Many commenters supported the proposal, in order to reduce State burden.

Response: We are finalizing the proposal. We remind issuers that offer both QHPs and non-QHPs in a market in a given State to submit its rate filing

[39] This standard (that is, the average increase for all enrollees weighted by premium volume meets or exceeds the applicable threshold), however, continues to apply to rates filed for coverage beginning before January 1, 2017, including with respect to compliance reviews and enforcement actions.

[40] 80 FR 10782.

in accordance with the deadlines established for QHPs to support regulatory review of compliance with the single risk pool requirement. Establishing a later submission deadline for issuers that offer only non-QHPs is a State option, not a requirement. We believe it will reduce burden while empowering States to pick the timeframe that works best for their markets, and also accounts for market differences between States. We also remind States and issuers that even if the submission deadlines differ; all information must be submitted to CMS by the earlier of the State deadline or the Federal deadline. We also remind States and issuers that only submission deadlines may vary; uniform posting will still be required, as discussed below, to help mitigate the potential for shadow pricing and other anti-competitive behaviors.

5. Determinations of Effective Rate Review Programs (§ 154.301)

a. State Posting of Rate Increases

We proposed to modify § 154.301(b)(2), by reducing the advance notification required, so that a State with an Effective Rate Review Program must notify us in writing, no later than 5 business days prior to the date it intends to make any proposed or final rate filing information public if the State will be posting prior to the date specified by the Secretary. We are finalizing this change as proposed.

Comment: The majority of commenters supported this proposal. Some commenters requested that CMS require States to inform issuers prior to posting. Some commenters requested that CMS require States to post rate filing information on State websites even if the information is also posted on CMS's website. Two commenters opposed the proposal because they interpreted the proposal as a reduction to the public's opportunity to review and comment.

Response: We appreciate the importance of State communication with issuers, and we expect States to maintain satisfactory communication regarding posting deadlines to issuers, but decline to propose requirements related to such. We also did not propose and are not making changes to the requirements regarding States posting on their own website. States are permitted to use CMS's website because we are mindful of the burden and cost associated with such posting, but we encourage States to consider posting rate filing information directly on their respective websites, while also providing a link to the CMS website. We are finalizing the proposal. This change will reduce the amount of time prior to posting that the State must notify CMS, but does not reduce the public comment period.

b. Posting of Rate Increases

Section 154.301(b)(3) provides that a State with an Effective Rate Review Program must ensure that information regarding rate increases is made available to the public at a uniform time for all proposed and final rate increases, as applicable, in the relevant market segment and without regard to whether coverage is offered on or off of an Exchange. That provision was codified in order to set a level playing field, to prevent issuers that submit rate filings later from having an advantage over their competitors that submitted rate filings earlier.

We proposed to eliminate the requirement for uniform posting so that States that have an Effective Rate Review Program would have the option to post proposed and final rate filing information on a rolling basis. We are not finalizing this proposal.

Comment: A few commenters supported the proposal, but the majority of commenters opposed the proposal, noting that uniform posting protects issuers from shadow pricing and ensures a level playing field in a fair competitive market. Those commenters were also concerned that posting on a rolling basis may promote manipulation by some market competitors, and could inadvertently contribute to market destabilization.

Response: We proposed to give States the option to post rate increase information on a rolling basis in order to accommodate a few States that have laws requiring immediate posting upon receipt. We did not receive overwhelming support for that change, as only two States supported it; the majority of commenters opposed the change. We agree with commenters' concerns that removing the requirement for uniform posting could have unintended, negative effects on competition in the markets. Some commenters also feared that posting on a rolling basis could cause confusion among consumers, and eliminate the likelihood of consumers easily comparing a rate increase across all products. We do not want to provide unfair advantages to issuers that file later in the filing season, or contribute to consumer confusion. Therefore, we are not finalizing the proposal. We are retaining § 154.301(b)(3) as it exists in our current regulations to require that a State with an Effective Rate Review Program ensure that the information in § 154.301(b)(1)(i) and (ii) is made available to the public at a uniform time for all proposed and final rate increases, as applicable, in the relevant market segment and without regard to whether coverage is offered on or off of an Exchange.

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

1. Standardized Options (§ 155.20)

In the 2017 Payment Notice, HHS introduced standardized options (also now referred to as Simple Choice plans). A standardized option is a QHP offered for sale through an individual market Exchange that either has a standardized cost-sharing structure specified by HHS in rulemaking or has a standardized cost-sharing structure specified by HHS in rulemaking that is modified only to the extent necessary to align with the high deductible health plan (HDHP) requirements under section 223 of the Code or the applicable annual limitation on cost sharing and HHS actuarial value requirements. For the 2017 and 2018 benefit years, HHS specified standardized options in rulemaking, encouraged issuers to offer such plans, and provided differential display of these plans on *HealthCare.gov*.

As noted in the proposed rule, we seek to encourage free market principles in the individual market, and to maximize innovation by issuers in designing and offering a wide range of plans to consumers. We noted concerns that providing differential display for these plans may limit enrollment in coverage with plan designs that do not match the standardized options, removing incentives for issuers to offer coverage with innovative plan designs. We believe that encouraging innovation is especially important now, given the stresses faced by the individual market. Therefore, we are finalizing our proposal to not specify any standardized options for the 2019 benefit year, and not to provide differential display for standardized options on *HealthCare.gov*. Agents, brokers, and issuers that assist consumers with QHP selection and enrollment as described in § 155.220(c)(3) and § 156.265(b), respectively, are also not required to provide differential display for standardized options on those third-party websites. We are finalizing the policies on standardized options as proposed.

Comment: Many commenters supported the proposed policy to discontinue standardized options for the 2019 plan year. Commenters noted that they believed standardized options

stifled issuers' ability to develop innovative plan designs. Commenters also noted that because of the differential display, issuers may have offered and consumers may have purchased HHS-designed plans that did not best meet consumers' needs. Other commenters noted that consumers may have mistakenly thought that standardized options were superior to other plans; and that other tools, such as AV, EHB, and other *HealthCare.gov* plan filters were sufficient in assisting consumers in selecting and comparing plans. Other commenters questioned the benefits of standardized options.

Many other commenters supported HHS continuing to specify standardized options, noting that they are a useful consumer-support tool that aids in plan comparisons and selection and that withdrawing the standardized options could create confusion for consumers, especially those with low health literacy or certain health conditions. Others noted that removing the standardized option designation could make plan selection more difficult resulting in fewer people enrolling in QHPs.

Some commenters noted that the standardized cost sharing encourages issuers to innovate on other plan features and encourages issuers to compete on networks and formularies. Other commenters noted that the standardized plan designs ensure offerings had certain desirable features, such as fewer specialty drug tiers and first dollar coverage. Commenters noted that standardized options were voluntary and therefore could not stifle innovation. Another commenter noted that removing standardized options could result in issuers designing plans specifically for a healthy population. Another commenter supported making standardized options mandatory and expanding to include SADPs.

Response: As we noted in the proposed rule, we believe that not specifying standardized options for the 2019 plan year will remove disincentives for issuers to offer coverage with innovative plan designs. We agree that issuers are in the best position to design and offer innovative plan designs. We are similarly finalizing the removal of the differential display of standardized options.

As we noted in the 2017 Payment Notice final rule,[41] we designed the standardized options to be as similar as possible to the most popular (weighted by enrollment) QHPs in the FFEs in order to minimize market disruption and impact on premiums. Consequently, we believe that the plan design features, such as annual limitations on cost sharing and deductibles, previously specified as part of standardized options are mostly available to consumers in FFEs. Therefore, we do not believe it is necessary to mandate or otherwise further provide an incentive for issuers to offer plans that meet the characteristics of standardized options.

We agree with commenters that *HealthCare.gov* plan filters for other tools are sufficient to enable most consumers to make plan selections. However, we continue to explore strategies to make shopping on *HealthCare.gov* as easy as possible, and to better support consumers in choosing coverage that is best for them. Consumers are able to select a QHP based on metal level, and are generally offered coverage of a similar set of essential health benefits. We agree with commenters that certain populations with specific health conditions may not purchase a QHP that best meets their needs if they merely select based on a standardized option designation. Standardized options offer simple plan comparisons at a high level to assess comparability on cost sharing of certain services. However, consumers with specific health conditions may be better served by a different QHP that provides benefits better suited for their individual needs. By removing standardized options, we are mitigating the risk that consumers with special coverage needs choose a standardized option plan that may not provide the optimal mix of cost-sharing protections, benefits, and networks for their situation. We believe these benefits outweigh any potential additional difficulty in selecting a QHP that could result from the elimination of the standardized option designation.

For these reasons we are finalizing the policy as proposed.

Comment: One commenter requested clarification that if the proposal is finalized as proposed standardized options would not appear on *HealthCare.gov* or be designated in public use files. Another commenter requested that HHS release data related to standardized options offerings and enrollment publicly prior to making a decision about ceasing to specify standardized options.

Response: The proposal is being finalized as proposed. Therefore standardized options will not display as ''Simple Choice Plans'' on *HealthCare.gov*, nor will information be collected and reported in public use files for the 2019 benefit year. We have previously released data regarding standardized options offerings in public use files. We believe releasing data regarding recent enrollment in standardized options could cause competitive harm to issuers, but intend to continue to release historical enrollment data for all QHPs, including standardized options, in the future.

Commenter: A commenter noted that standardized options assist States in Federal and State review, certification, and oversight.

Response: States have previously been able to complete QHP certification, review, and oversight for issuers that are not offering standardized options, and therefore, we believe that they will be able to continue doing so without relying on standardized options.

2. General Standards Related to the Establishment of an Exchange

a. Flexibility for State Exchanges and State Exchanges on the Federal Platform (§ 155.106 and § 155.200)

While the PPACA allowed each State to operate its own State Exchange, currently 11 States and the District of Columbia operate their own Exchanges, five States utilize the SBE–FP model, and FFEs operate in the remaining 34 States. We seek to support innovation by States operating State Exchanges by providing opportunities for increased program flexibilities to help support the retention and financial self-sustainability of States that adopted the SBE model. In particular, we sought comment on how HHS can best support State Exchange efforts to utilize commercial platform services, including what type of technical support would be useful and what, if any, specific regulatory changes would facilitate the use of these services.

We also proposed to explore strategies to make the SBE–FP model more appealing and viable to States with FFEs, as well as to support retention of existing SBE–FPs. As codified in the 2017 Payment Notice, the SBE–FP model allows States to establish the legal status of their Exchanges as State Exchanges while leveraging the economies of scale available through the Federal eligibility and enrollment platform and information technology infrastructure. The SBE–FP model offers States opportunities to retain more control over their Exchanges than if an FFE operated in the State, as it allows them to control plan management and consumer assistance activities, without the additional responsibility of building the infrastructure required to operate an information technology eligibility and enrollment platform. Accordingly, we seek to explore options for streamlining current requirements and leveraging private sector and Federal platform

[41] 81 FR at 12289 (March 8, 2016).

technologies and advances to increase opportunities for those States interested in remaining or becoming SBE–FPs. We also intend to continue to explore areas where current authority, technology, and operational capacities would permit HHS to provide additional options in operational functions to SBE–FPs and provide SBE–FPs with a greater role in decision-making. We sought comment on ways to strengthen and enhance the SBE–FP model.

Comment: Several commenters supported further actions by HHS to allow SBE–FPs greater access to enrollment data and consumer assistance tools, and supported efforts to customize the Federal platform to meet SBE–FP needs. Other commenters encouraged HHS to lower or eliminate the SBE–FP user fee, increase predictability of the user fee, or to tailor the user fee to an Exchange based on use of certain Federal platform options. One commenter proposed HHS consider new Federal grant funding for State Exchanges to purchase commercial technology platforms, while others requested HHS reduce market uncertainty and further streamline eligibility verification requirements to support the success of SBEs. Another commenter requested that HHS promote regional State Exchanges to mitigate financial sustainability challenges faced by smaller States. Several commenters encouraged the use of direct enrollment and enhanced direct enrollment capabilities and private and Federal platform technologies by State Exchanges and SBE–FPs. One commenter suggested State Exchanges consolidate into a single entity utilizing Federal platform technology while enabling private partnerships and non-profit entities to perform consumer facing functions. Two commenters suggested the Federal platform include functionality to support independent enrollment in dental plans in SBE–FPs.

Other commenters supported the concepts of innovation and increased customization of the Federal platform, but suggested HHS prioritize improvements to the overall *HealthCare.gov* system infrastructure before focusing on State-specific enhancements to *HealthCare.gov*. Some commenters emphasized the need for guardrails to protect patients and consumers as HHS explores flexibilities and innovations in Exchange models. One commenter expressed concern that HHS's support for expanding the SBE–FP model signaled an intent to reduce Federal support for small population States and requested assurance the FFE would continue to be available for small States.

Response: We appreciate the comments, and will consider them as we continue to explore incentives and program flexibilities for the SBE and SBE–FP models. The SBE–FP model was intended to improve States' ability to operate efficient Exchanges by providing the option for State Exchanges to agree to rely on the Federal eligibility and enrollment platform and information technology infrastructure to carry out certain functions in order for the State to fulfill requirements as a State Exchange. We continue to explore ways to make this a more appealing option to States that currently have FFEs. In 2017, at the request of the SBE–FPs, we shared new data with the SBE–FPs to enhance their consumer outreach functions, customer relationships, and fiscal planning activities. HHS intends to continue to enhance these data-sharing efforts with SBE–FPs to support their ability to fulfill their responsibilities. However, at this time, HHS is unable to offer a menu of Federal platform functionalities to an SBE–FP. Likewise, at this time, HHS is unable to offer State-specific customization of the Federal platform agreement, but will continue engaging with SBE–FPs to refine the agreement. We also note that § 155.140 permits States to participate in regional Exchanges spanning two or more States. This allows States interested in operating State Exchanges to partner with each other and leverage economies of scale by sharing a common information technology infrastructure or platform, and HHS encourages States to explore this as an option. States that are interested in this option would need to obtain HHS approval to operate as a regional Exchange, fulfill the requirements under § 155.140, and meet the functional requirements in 45 CFR part 155 that are applicable to States who wish to operate their own SBE. We also note that HHS has provided the authority and flexibility for SBEs to utilize the direct enrollment pathway as an alternative option for enrolling consumers into SBEs. HHS continues to encourage SBEs and SBE–FPs to explore this option in the context of evaluating options that best suit the needs of their Exchange, State, and consumers.

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

Section 155.106 describes the process for a State electing to operate a State Exchange, terminating its State Exchange and transitioning to an FFE, or seeking to operate an SBE–FP. This section applies to both individual market and SHOP Exchanges. Currently, under § 155.106(c), as finalized in the 2017 Payment Notice, States can elect to operate an individual market SBE–FP, an SBE–FP for SHOP, or both. If a State operates an SBE–FP for SHOP, the SBE–FP utilizes the Federal platform for enrollment, eligibility, and premium aggregation functions.

As discussed more fully in section III.D.9 of this final rule, we proposed changes to required SHOP functionality, effective on the effective date of this rule, for plan years beginning on or after January 1, 2018, under which qualified employers and employees could enroll in SHOP plans by working with a QHP issuer or SHOP-registered agent or broker. As a result of the finalization of these proposals, many Federal platform functions currently available to a State operating an SBE–FP for SHOP will no longer exist, including employee eligibility, enrollment, and premium aggregation functions. Therefore, States operating an SBE–FP for SHOP will no longer be able to utilize the Federal platform for those functions.

We proposed to amend § 155.106(c) to remove the option for States to seek approval to operate an SBE–FP for SHOP after the effective date of this rule, and are finalizing the policy as proposed. Nonetheless, States that are currently operating an SBE–FP for SHOP, which include Kentucky and Nevada, can choose to maintain their existing SBE–FPs for SHOP, using the Federal platform functionality that would remain, subject to the applicable requirements in § 155.200(f)(4), which we are amending to align with the changes to SHOP functionality requirements. Issuers in these SBE–FPs for SHOP will continue to be subject to § 156.350, which we are amending to align with the changes to SHOP functionality requirements. For those issuers that offer SHOP QHPs in SBE–FPs for SHOP beginning on or after January 1, 2018, the expected burden (as well as expected reduction in burden) should be similar to that of issuers in the FF–SHOPs.

Comment: One commenter suggested HHS should consider continuing to permit States to elect to operate as an SBE–FP for SHOP, to increase the type of Exchange models available to States. Otherwise, we did not receive substantive comments regarding the proposed changes to § 155.106.

Response: As described above, as a result of the finalization of the SHOP proposals described in this rule, the SHOP Federal platform currently available to a State operating an SBE–FP for SHOP will essentially no longer exist, including the Federal platform functions of employee eligibility, enrollment, and premium aggregation

on which SBE–FPs for SHOP currently rely. Therefore, States operating an SBE–FP for SHOP will no longer have an option to rely on the Federal platform for those functions. We are finalizing the policy as proposed, with a minor, non-substantive change to the regulatory text.

c. Additional Required Benefits (§ 155.170)

Section 1311(d)(3)(B) of the PPACA permits a State, at its option, to require QHPs to cover benefits in addition to the EHB, but requires a State to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional State-required benefits. In previous rulemaking, we directed States to identify additional State-required benefits that are subject to defrayal and provided direction on how QHP issuers in a State must calculate the cost of those benefits.[42]

We made a number of proposals at § 156.111 related to State changes to EHB-benchmark plans beginning for the 2019 plan year. In light of those proposed changes, we stated that we were not proposing any changes to the policies governing State-required benefits at § 155.170. That is, whether a benefit mandated by State action could be considered EHB would continue to depend on when the State enacted the mandate (unless the benefit mandated was for the purposes of compliance with Federal requirements). Under any of the proposed methods for a State to select a new EHB-benchmark plan, benefits mandated by a State action *prior to or on December 31, 2011* would be considered EHB in that State according to the continuing policy described above and would not require State defrayal. However, State-required benefits mandated by State action taking place *after December 31, 2011,* other than for purposes of compliance with Federal requirements, would continue to be considered in addition to EHB even if embedded in the State's newly selected EHB-benchmark plan under the proposals at § 156.111. Therefore, their costs would be required to be defrayed by the State.

As discussed more fully in the preamble for § 156.111, we proposed that § 155.170 would continue to apply in the same manner as it currently applies to § 156.110, and that the proposed § 156.111, which offers States the flexibility to select a new EHB-benchmark plan, would not remove the obligations required with regard to maximum allowed generosity for a State's EHB-benchmark plan. For further discussion of how the State mandate policy at § 155.170 would apply to EHB under the proposals at § 156.111 providing States with options to select a new EHB-benchmark plan for plan years beginning in 2020 and later, see the preamble to § 156.111.

We sought comments on this approach. Specifically, we were interested in comments on different applications of the State mandate policy to the proposed policy for EHB-benchmark plan selections at § 156.111 that would increase State flexibility while also being cost effective for States, consumers, and the Federal government, such as an approach that would allow States the flexibility to update benefits mandated by State action prior to or on December 31, 2011, that are considered EHB, so long as the State can prove that the update to the State mandate is budget neutral.

In this final rule, we are finalizing the approach described above of not making changes to the policy under § 155.170.

Comment: Many commenters requested changes to the policies governing State-required benefits at § 155.170 in light of new EHB-benchmark plan selection options established at § 156.111. Some of these commenters were concerned about States selecting a more generous benchmark plan under the proposed options at § 156.111(a) that could reduce affordability by allowing the selecting State to include another State's mandates in its benchmark plan and thereby allow the selecting State to indirectly adopt another State's mandates *without* defrayal. These commenters recommended that States be required to defray the costs of any additional required benefits that result from the selection of a new EHB-benchmark plan if those benefits are more generous than the State's previous EHB-benchmark plan, regardless of whether the additional benefits were put in place by the newly-selected EHB-benchmark plan or were the result of benefits mandated by State action in the selecting State. Other commenters were concerned that the current policy of requiring States to defray the costs of State-required benefits mandated after December 31, 2011, other than for purposes of compliance with Federal requirements, would prevent States from updating benefits in response to medical advances and their population's changing needs. These commenters requested that HHS create a public process for States to consider new State-required benefits as EHB without additional cost to the State. Other commenters opposed requiring States to defray mandated benefits at all, because the policy discourages States from ensuring access to key health care services for consumers—such as autism and opioid dependency disorder services. Several commenters supported the proposal to maintain the policies at § 155.170, noting that section 1302(b)(4)(H) of the PPACA grants the Secretary flexibility to update EHB benefit categories as it becomes necessary to do so. Other commenters believed that a stricter standard regarding defrayal is needed to ensure that States comply with the current defrayal requirement at § 155.170, and to ensure that a sufficient defrayal requirement is in place based on new State EHB-benchmark plan selection options at § 156.111.

Response: We understand the importance of benefit mandates to States under the policies described above. With the finalization of the State's new EHB-benchmark plan options at § 156.111, States will continue to have the authority to implement benefit mandates as part of EHB, in accordance with § 155.170.

Specifically, if a State selects a new EHB-benchmark plan under any of the options finalized in this rule at § 156.111, the benefits mandated by the selecting State's action prior to or on December 31, 2011 will continue to be considered EHB and will not be subject to defrayal, in accordance with § 155.170. If the State is selecting from another State's EHB-benchmark plan under the first or second option, as discussed in preamble to § 156.111, and the selected EHB-benchmark plan (or category of services) includes benefits mandated by the State from which the plan originated that are EHB, those benefits will also be incorporated into the selecting State's EHB-benchmark plan without a requirement that the selecting State defray their related costs, unless the selecting State has its own mandates regarding these same benefits and those mandates meet the requirements for defrayal in § 155.170.

Relatedly, our decision to maintain the policies governing State-required benefits at § 155.170 is motivated by our goal to provide States with more flexibility and reduce administrative burden for selecting a new EHB-benchmark plan under Option 1 or 2 described in § 156.111. Specifically, we believe that many benefits that are State mandates are likely already embedded

[42] *See* 155.170(b) and (c). *Also see* the EHB Rule, available at *https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf*, the 2016 Payment Notice Final Rule, available at *https://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf,* and the 2017 Payment Notice Final Rule, available at *https://www.gpo.gov/fdsys/pkg/FR-2016-03-08/pdf/2016-04439.pdf.*

in States' existing 2017 EHB-benchmark plans, and removing them would be complicated for a selecting State. In particular, we are concerned that this additional level of effort would create a barrier to States trying to select another State's 2017 EHB-benchmark plan under Options 1 or 2 being finalized at § 156.111(a)(1) and (2), particularly when several types of benefits mandated by State action overlap with one of the ten EHB categories. More specifically, because benefits mandated by State action are generally EHB if the mandates were enacted on or before December 31, 2011, and the 2017 EHB-benchmark plans that are used for the options under § 156.111 are based on base-benchmark plans that were available in 2014, we believe that the majority of benefits mandated by State action that are EHB in accordance with § 155.170 are already embedded in the originating State's EHB-benchmark plan documents.

We also note that we are finalizing that all options for a State to select a new EHB-benchmark plan described in § 156.111 are limited by a generosity standard. This generosity standard will limit the State's ability to increase the overall scope of benefits in its EHB-benchmark plan beyond the generosity of a set of comparison plans that includes a State's 2017 EHB-benchmark plan and any of the State's base-benchmark plan options for the 2017 plan year described in § 156.100(a)(1), supplemented as necessary under § 156.110. In practice, this requirement limits States' overall ability to select a new EHB-benchmark plan that transfers benefits that were previously only applied to the State's large group market, or that were mandated by other States' actions prior to 2012, into its new EHB-benchmark plan. As a result, we believe that this approach balances our goal to promote State flexibility with the need to preserve coverage affordability. For additional discussion on considerations related to § 155.170 for States that select a new EHB-benchmark plan using an option described at § 156.111, see the preamble to section § 156.111.

3. General Functions of an Exchange

a. Functions of an Exchange (§ 155.200)

The 2017 Payment Notice finalized requirements at § 155.200(f)(2) for SBE–FPs to establish and oversee certain requirements for their QHPs and QHP issuers that are no less strict than the requirements that apply to QHPs and QHP issuers on an FFE. Due to the operational complexities in implementing these requirements from both the State and Federal perspective, and to promote the goal of returning regulatory authority over the insurance markets to States, we proposed to eliminate requirements for SBE–FPs to enforce FFE standards for network adequacy at § 155.200(f)(2)(ii) and essential community providers at § 155.200(f)(2)(iii). Instead, we proposed that the SBE–FPs, like other State Exchanges, would have the flexibility to determine how to implement the network adequacy and essential community provider (ECP) standards with which issuers offering QHPs through the SBE–FP must comply. We believe SBE–FPs are best positioned to determine these standards for the QHP certification process in their States, and that the removal of the requirement that SBE–FPs establish and oversee requirements for their issuers that are no less strict than the manner in which these regulatory requirements are applied to FFE issuers would streamline certain aspects of the QHP certification process, and return traditional insurance market regulatory authority to the States. Additionally, HHS proposed that, for 2019 plan years and later, the FFEs would rely on State reviews of network adequacy standards where the States have been determined to have an adequate review process. Accordingly, we believe similar deference should be granted to States with SBE–FPs. We believe these changes will further empower SBE–FPs to use their QHP certification authority to encourage issuers to stay in the Exchange, enter the Exchange for the first time, or expand into additional service areas. We are finalizing these changes as proposed.

We also proposed to remove the requirement at § 155.200(f)(2)(iv) that QHP issuers in SBE–FPs comply with the Federal meaningful difference standard to reflect the removal of § 156.298 described elsewhere in this rule. We are finalizing this change as proposed.

Comment: Several commenters opposed eliminating requirements for SBE–FPs to enforce FFE standards for network adequacy at § 155.200(f)(2)(ii) and ECPs at § 155.200(f)(2)(iii) for the 2019 benefit year and beyond. They urged HHS to continue requiring SBE–FPs to enforce these FFE standards, stating that some State Exchanges that do not currently use the Federal platform have adopted less robust network adequacy and ECP standards, which are critical to providing access to providers that serve vulnerable populations. Other commenters supported this proposal if the States have an adequate review process, and encouraged HHS to monitor State oversight of networks to ensure that the States in fact have the capacity to ensure health plan compliance. Other commenters supported this proposal, stating that they believe networks are best developed and regulated at the State level to allow for variations in State geography, demographics, and market conditions.

Response: We are finalizing the proposal to remove the requirement that SBE–FPs establish and oversee requirements for their issuers that are no less strict than the manner in which these regulatory requirements are applied to FFE issuers. We believe SBE–FPs are best positioned to determine these standards for the QHP certification process in their States, and elimination of this requirement would streamline certain aspects of the QHP certification process by reducing oversight burden on SBE–FPs.

Section 155.200(f)(4) describes requirements for States that operate an SBE–FP for SHOP. As discussed earlier in this preamble, although we proposed that States can no longer elect to operate SBE–FPs for SHOP after the effective date of this rule, which we are finalizing as proposed, Kentucky and Nevada are already approved to operate SBE–FPs for SHOP, and thus the requirements in § 155.200(f)(4) remain relevant for those SBE–FPs for SHOP. Therefore, we proposed to amend § 155.200(f)(4) to reflect the proposed amendments (described in section III.D.9 of this final rule) under which the functionality of the FF–SHOPs' platform would be reduced for plan years beginning on or after January 1, 2018. Specifically, we proposed to amend the introductory text to § 155.200(f)(4) to describe the requirement applicable, effective on the effective date of this rule for plan years beginning on January 1, 2018 and beyond, and to make the requirements in paragraphs (f)(4)(i) through (vii), effective on the effective date of this rule applicable for only plan years beginning prior to January 1, 2018.

Specifically the requirements in (f)(4)(i) and (iv), which require SBE–FPs for SHOP to align their premium payment and employer contribution calculation methodologies with those used by the Federal platform, would not apply for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. Because under our amendments to § 155.705 and newly finalized § 155.706, for plan years beginning on or after January 1, 2018, the Federal platform for SHOP will no longer calculate premium rates or employer contributions, and will no longer aggregate premium payments (as of the effective date of the final rule),

there will be no further need for such alignment for plan years beginning on or after January 1, 2018.

Because under the approach we are finalizing, the Federal platform will continue to include plan display with premium amounts, we did not propose changes to the requirement that States operating an SBE–FP must require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a Federally-facilitated SHOP under current § 155.705(b)(6)(i)(A), which regulation is mirrored in our proposed introduction of § 155.706(b)(6)(i)(A). However, we proposed to specify that this requirement applies in the introductory text to (f)(4), to reflect the proposed change to make the requirements in (f)(4)(i) through (vii) applicable for only plan years beginning prior to January 1, 2018, effective on the effective date of this rule.

Additionally, because under the approach we are finalizing, for plan years beginning on or after January 1, 2018, the Federal platform will, effective on the effective date of this rule no longer calculate whether a qualified employer has met the applicable minimum participation rate, there will no longer be any need for States operating an SBE–FP for SHOP to align their minimum participation rate requirements and calculation methodologies with those applicable in the FF–SHOPs for plan years beginning on or after January 1, 2018. Therefore, we proposed that this requirement would only apply for plan years beginning prior to January 1, 2018, effective on the effective date of this rule.

To align with our amendments at § 155.725 and newly finalized § 155.726, under which the FF–SHOPs, effective on the effective date of this rule, for plan years beginning on or after January 1, 2018, will no longer establish annual employee open enrollment periods, or establish effective dates of coverage for an initial group enrollment or group renewal, we also proposed that the requirements in § 155.200(f)(4)(v) and (vi) would only apply for plan years beginning prior to January 1, 2018, effective on the effective date of this rule. Finally, to align with our amendments at § 155.735, under which the FF–SHOP, effective on the effective date of this rule for plan years beginning on or after January 1, 2018, will no longer determine the timing, form, and manner in which coverage or enrollment in a SHOP QHP may be terminated, we proposed that the requirement in § 155.200(f)(4)(vii) would only apply for plan years beginning prior to January 1, 2018, effective on the effective date of this rule.

We are finalizing as proposed the changes to § 155.200. Substantive comments related to SHOP proposals are summarized in section III.D.9 of this final rule.

b. Navigator Program Standards (§ 155.210)

Each Exchange is required under section 1311(d)(4)(K) and 1311(i) of the PPACA to establish a Navigator program under which it awards grants to entities that, among other things: Conduct public education activities to raise awareness of the availability of QHPs, distribute fair and impartial information concerning enrollment in QHPs and the availability of PTCs and CSRs, and facilitate enrollment in QHPs. Under section 1311(i)(2)(B) of the PPACA, these entities may include trade, industry, and professional associations; commercial fishing industry organizations; ranching and farming organizations; community and consumer-focused nonprofit groups; chambers of commerce; unions; resource partners of the Small Business Administration; other licensed insurance agents and brokers; and other entities that meet the statutory requirements at section 1311(i)(3), (4), and (5) of the PPACA.

Currently, § 155.210(c)(2) specifies that each Exchange must include among its Navigator grantees both a community and consumer-focused nonprofit group and at least one other entity that is from one of the other categories listed at § 155.210(c)(2), including other public or private entities or individuals that meet the requirements of § 155.210. Section 155.210(c)(2)(viii) specifies that these other entities may include Indian tribes, tribal organizations, urban Indian organizations, and State or local human service agencies.

To maximize the flexibility and efficiency of the Navigator program, we proposed to amend § 155.210(c)(2) to remove the requirements that each Exchange must have at least two Navigator entities and that one of these entities must be a community and consumer-focused nonprofit group. As discussed further below, we are finalizing this amendment as proposed. We believe removing these requirements will provide Exchanges with improved flexibility to award funding to the number and type of entities that will be most effective for the specific Exchange. We believe that eliminating the requirement to have at least two Navigator entities will allow each Exchange to optimally use the funding amounts available to direct investments to effective and efficient Navigators, which may include selecting a single, high performing grantee in an Exchange.

The requirement that one Navigator grantee in each Exchange must be a community and consumer-focused nonprofit group may unnecessarily limit an Exchange's ability to award grants to the strongest applicants, particularly in an Exchange that opts under this final rule to have only one Navigator grantee and where the strongest applicant is not a community and consumer-focused nonprofit group. Keeping this requirement would effectively exclude any other type of statutorily eligible entities from becoming Navigators in an Exchange that opts to have only one Navigator grantee. Eliminating this requirement will provide Exchanges with the flexibility to target grants to the highest scoring and performing entities, regardless of organization type.

Removing these requirements at § 155.210(c)(2) will also promote Exchange flexibility and autonomy to structure Navigator programs tailored to each Exchange. An Exchange could award a grant to a single Navigator entity from any of the permitted types. Alternatively, Exchanges could elect to continue awarding two or more grants, as they have been doing thus far, and include a community and consumer-focused nonprofit group among those grantees.

Section 155.210(e)(7) requires each Navigator entity to maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. We proposed to remove this requirement to provide more flexibility to each Exchange to structure its Navigator program to best serve the Exchange service area, and as discussed further below, are finalizing this amendment as proposed. Under section 1311(i)(2)(A) of the PPACA and § 155.210(c)(1)(ii), entities seeking to become Navigator grantees must demonstrate to the Exchange that they have existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible for enrollment in a QHP. Consistent with those provisions, Navigator grant applicants in the FFEs are scored on their ability to make this demonstration. Based on HHS's experience with Navigator programs in FFEs and other public programs, we believe entities with strong relationships in their FFE service areas tend to deliver the most effective outreach and enrollment

results. However, we believe that each Exchange is best suited to determine the weight to give a physical presence in the Exchange service area when selecting Navigator entities, as long as the Exchange's Navigator grantee selection process is consistent with section 1311(i)(2)(A) of the PPACA and § 155.210(c)(1)(ii).

For reasons similar to those motivating our proposed changes to § 155.210(e)(7), as well as to promote consistency across programs, we proposed to remove the corresponding requirement at § 155.215(h) that requires maintenance of a physical presence in the Exchange service area by all non-Navigator entities subject to § 155.215. We are also finalizing this amendment as proposed.

In addition to the requirement to maintain a physical presence in the Exchange service area, §§ 155.210(e)(7) and 155.215(h) currently provide that, in an FFE, no individual or entity is ineligible to operate as a Navigator or non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area. We did not propose to amend or remove that language, and it will remain in effect.

In addition to seeking comment on the proposed amendments described above, we also sought comment on statutorily acceptable alternative types of entities that could serve as Navigators and on possible new ways in which Navigators could carry out their duties.

Comment: We received comments in support of removing the requirement that each Exchange must have at least two Navigator entities. Several commenters believed that adopting this change could assist HHS with ensuring that Navigator grants are expended efficiently and effectively. Many commenters, however, expressed concern about reducing the number of required Navigator entities per Exchange, conveying that removing this requirement could potentially negatively affect consumer access to in-person assistance, and therefore make it harder for consumers to understand their coverage options and enroll in health coverage. Several commenters suggested that having two Navigator entities per Exchange ensures that an Exchange can have a general entity and one more tailored to specific needs within an Exchange, such as a focus on young adults, limited English proficient individuals, or other targeted populations.

Response: We agree with commenters who stated that removing these requirements will provide Exchanges with improved flexibility to award funding to the number and type of entities that would be most effective for each specific Exchange. We appreciate the importance of consumer access to experienced, in-person assistance, and believe this change will allow each Exchange to optimally use available funding amounts, such as by selecting a single, high-performing grantee in an Exchange. In this way, we do not believe this change will have a detrimental effect on the availability of professional, unbiased, in-person consumer assistance. Additionally, the proposal does not require an Exchange to have only one Navigator. It simply provides Exchanges with that option. We are finalizing this change as proposed.

Comment: We received comments in support of removing the requirement that each Exchange must have one Navigator entity that is a community and consumer-focused nonprofit. Several of these commenters supported HHS's promotion of Exchange flexibility with this change. However, many commenters expressed concern about removing this requirement, conveying that Navigators, and in particular independent, nonprofit Navigators, have proven to be a critical resource for helping consumers enroll in coverage that is appropriate for their needs in previous enrollment periods. Many commenters stated that nonprofit Navigator entities are unique among other types of Navigator groups because they typically have expertise with one or more hard-to-reach populations within their communities, such as veterans, limited English proficiency individuals, or other targeted populations, and have the trust of many community members. In addition, commenters suggested that this requirement was initially added to address concerns about fraud, abuse, and the difficulty that Exchanges faced overseeing other types of Navigator entities.

Response: We agree with commenters who emphasized the importance of funding nonprofit Navigator entities, and also agree that nonprofit Navigator entities often have expertise with one or more hard-to-reach populations within their communities. Nothing in this rule prevents an Exchange from selecting and funding a nonprofit Navigator entity if it determines that such an entity best meets the needs of the community served by the Exchange. However, we also recognize that there are circumstances in which another type of entity may be the strongest applicant. In these cases, an Exchange that chooses to have only one Navigator grantee (as permitted by the change finalized in this rule), would be unable to select its strongest applicant absent a change to the requirement that one Navigator grantee in each Exchange must be a community and consumer-focused nonprofit group. We also agree with commenters that removing this requirement will support Exchange flexibility and autonomy to structure Navigator programs tailored to each Exchange and target grants to the highest scoring and performing entities, regardless of organization type. We believe that Exchanges are well-situated to determine the proper use of the funding amounts available and are able to determine the type of entity or entities that will serve their Exchange service areas best. We are finalizing this change as proposed.

Comment: We received comments in support of removing the standard requiring Navigators to maintain a physical presence in the Exchange service area. Several commenters believed that removing this requirement will provide Exchanges with greater flexibility and enable them to expand options for consumer support. On the other hand, many commenters believed that entities not physically present in an Exchange service area may not be able to provide a full spectrum of local outreach, education, and assistance to support enrollment and post-enrollment activities. Many commenters suggested that removing this requirement would negatively affect hard-to-reach populations, as the in-person assistance provided by Navigator entities is often the only known resource and form of support for some low-income and other at-risk populations. In addition, some commenters believe that web or phone-based assistance is a poor substitute for in-person assistance delivered by a known and trusted community-based organization, and that this is particularly true for those living with significant health needs for whom remote assistance may prove inadequate and frustrating.

Response: We agree with commenters who emphasized the importance of providing more flexibility to each Exchange to structure its Navigator program to best serve the Exchange's service area. As we stated in the proposed rule, we believe that entities with a physical presence and strong relationships in their FFE service areas tend to deliver the most effective outreach and enrollment results. Nothing in this final rule prevents an Exchange from selecting grantees that are physically present and available to provide a spectrum of in-person, local outreach, education, and assistance, including directing these services

towards vulnerable and hard-to-reach populations, if the Exchange elects to weight its selection process in that way and its selection process is consistent with section 1311(i)(2)(A) of PPACA and § 155.210(c)(1)(ii). Furthermore, we believe that there are various organizations that might prove to be promising partners in the delivery of both local and remote consumer assistance with regard to health coverage enrollment and education. While in-person assistance may be more helpful than remote services in some situations, we believe that determining which entities are well-situated to serve consumers within a particular Exchange is best left up to each Exchange. By allowing Exchanges greater flexibility, each Exchange will be better able to ensure that its service area can be assisted by the entity or entities that best fits the needs of its population. We are finalizing this change as proposed.

Comment: We received comments about the potential use of other entities to provide enrollment assistance or remote services to consumers, beyond Navigator entities. Some commenters conveyed that other types of organizations are well-situated to provide enrollment assistance, such as local agents and brokers and direct enrollment partners. Some commenters believe that an approach to consumer assistance that leverages experts from different types of organizations that have strong ties to the community is a comprehensive way to provide consumers with the best available expertise.

Response: We agree that local collaboration and leveraging community partnerships can help in reaching marginalized communities. For FFEs, we will take these comments into consideration when drafting Navigator selection criteria for Navigator funding opportunity announcements in future years. While agents, brokers, and direct enrollment partners might in many cases not be eligible to become Navigators due to statutory limitations on Navigator eligibility at section 1311(i)(4) of PPACA, we also agree that agents, brokers, and direct enrollment partners can be well situated to provide enrollment assistance or remote services to consumers, and we intend to continue to work with these stakeholders to ensure consumers in FFEs have access to a range of enrollment assistance, including Navigators.

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

For a discussion of the provisions of this final rule related to standards applicable to non-Navigator Assistance Personnel subject to § 155.215, please see the preamble to § 155.210.

d. Standards for Third-Party Entities To Perform Audits of Agents, Brokers, and Issuers Participating in Direct Enrollment (§ 155.221)

HHS proposed new standards in the proposed rule to replace the standards set forth in the 2018 Payment Notice for § 155.221 for third-party onboarding operational readiness reviews and audits for direct enrollment partners. HHS also proposed to expand the applicability of this section to require issuers, in addition to agents and brokers, participating in direct enrollment to engage third-party entities to conduct the required operational readiness reviews. We proposed a conforming edit to § 156.1230(b)(2) to reflect this proposal.

HHS proposed to implement an approach wherein agents, brokers, and issuers that participate in direct enrollment and use their own internet website for QHP selection or to complete the Exchange eligibility application would select their own third-party entities for conducting audits, rather than requiring HHS to initially review and approve these entities. As detailed in the proposed rule, HHS anticipates this approach would reduce the regulatory burden for agents, brokers, and issuers, and reduce duplicative HHS oversight. This approach will also reduce the burden on third-party entity reviewers.

Beginning with the open enrollment period for the 2019 benefit year, we proposed that an agent, broker, or issuer must engage a third-party entity that meets the standards outlined in the new § 155.221(b) to conduct an annual operational readiness review prior to participating in direct enrollment. Consistent with § 155.220(c)(3)(i)(K) and § 156.1230(b)(2), the operational readiness review would be performed using the third parties' own audit processes and methods subject to HHS-defined specifications and requirements. The third-party entity's review would verify compliance by the agent, broker, or issuer with the applicable requirements in §§ 155.220, 155.260, 156.265, and 156.1230, and would need to be completed prior to the use of the agent, broker, or issuer internet website for submission of an Exchange application or completion of QHP selection. HHS would publish technical guidance outlining the review standards and other operational details, as well as provide other resources to assist the third-party entities in conducting the reviews at a later date. As outlined in the last sentence of the new § 155.221(a), the third-party entity would be a downstream or delegated entity of the agent, broker, or issuer that participates or wishes to participate in direct enrollment. Therefore, these third-party entities would be subject to HHS oversight as delegated or downstream entities of an agent, broker, or issuer, and the agent, broker, or issuer will remain responsible for compliance with all applicable direct enrollment requirements.

We also proposed revisions to § 155.221(b), which establishes standards that third-party entities must satisfy to perform the reviews to demonstrate operational readiness under § 155.220(c)(3)(i)(K) and § 156.1230(b)(2), beginning with the open enrollment period for the 2019 benefit year. The proposed new introductory language at § 155.221(b) aligns with the new approach where the agent, broker, or issuer selects the third-party entity to perform the audit under paragraph (a). As proposed, new § 155.221(b)(1) would require the entity to have experience conducting audits or similar services, including specific experience with relevant privacy and security standards due to the operational requirements of the current direct enrollment processes and any potential future enhancements. This would include demonstrated experience with current National Institute of Standards and Technology (NIST) SP 800–53 or the HIPAA Security Rule standards, and the review of compliance with those standards. We proposed that auditors must also be capable of performing penetration testing on all interfaces that collect personally identifiable information or connect with HHS. We proposed to modify § 155.221(b)(2) to include issuers participating in direct enrollment and to expand the scope of the audit to also include review of compliance with other applicable program requirements (for example, website design, or consumer disclosures). Under proposed § 155.221(b)(3), auditors would be required to collect, store, and share with HHS all data related to its audits of

agents, brokers, and issuers under paragraph (a) in a manner, format, and frequency specified by HHS until 10 years from the date of creation, and would be required to comply with the privacy and security standards HHS adopts for agents, brokers, and issuers as required in accordance with § 155.260.

The proposed revisions to paragraph (b)(4) would implement a conflict of interest standard that requires disclosure of financial relationships between a third-party entity conducting a direct enrollment operational readiness review and the agent, broker, or issuer. In addition, the third-party entity would be required, under § 155.221(b)(5), to comply with all applicable Federal and State requirements; under § 155.221(b)(6), to ensure, on an annual basis, that appropriate staff successfully complete operational readiness review training as established by HHS prior to conducting audits under paragraph (a) of this section; and, under § 155.221(b)(7), to permit access by the Secretary and the Office of the Inspector General (OIG), or their designees, in connection with their right to evaluate through audit, inspection, or other means, to the third-party entity's books, contracts, computers, or other electronic systems, relating to the third-party entity's audits of agents, broker's, or issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the date of creation. Finally, to provide flexibility, under § 155.221(c) an agent, broker, or issuer would be permitted to engage multiple third-party entities to perform the audits under paragraph (a) and each such third-party entity would need to separately comply with the standards under paragraph (b). We are finalizing these amendments as proposed, with a minor, non-substantive change described below.

Comment: Most commenters were concerned that enrollment through a non-governmental site would occur without proper oversight and controls. They expressed concern about the potential for fraud, or the possibility that agents, brokers, and issuers would unfairly direct consumers to QHPs with which the agent, broker, or issuer, had an existing relationship. Additionally, a number of commenters were concerned about the potential for conflicts of interest arising from relationships between the agents, brokers, and issuers and the third-party auditors they select to conduct their audits.

Response: We are finalizing the modifications to § 155.221 as proposed, with a minor non-substantive edit to paragraph (b)(7) to remove the acronym ''OIG''. We have put in place guidelines and processes to oversee the activities of agents, brokers, and issuers participating in direct enrollment, and anticipate continuing to monitor enrollments through the direct enrollment pathway for evidence of fraud or abuse. While we acknowledge the potential for conflicts of interest, we believe the required disclosures, continuous monitoring and oversight, and standards established for third-party auditors will sufficiently mitigate these concerns. Furthermore, we believe the requirements being finalized in this rule will ensure that quality operational readiness reviews are conducted. Lastly, we agree that it is important that consumers enrolling using direct enrollment be able to make informed decisions about coverage. We believe § 155.220, which establishes standards that apply when Exchange consumers select an individual market QHP through an agent's or broker's website, including a requirement that agents and brokers engaged in direct enrollment display all QHP data provided by the Exchange, will help promote informed consumer choice about all available QHPs, not just those with which the agent or broker has an existing relationship.

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

a. Eligibility Standards (§ 155.305)

Section 155.305(f)(4)(i) prohibits an Exchange from determining 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 married) for a previous year for which tax data would be used for verification of household income and family size, and the tax filer or his or her spouse did not comply with the requirement to file an income tax return and reconcile APTC paid on their behalf that year. Under the current regulation at paragraph (f)(4)(ii), Exchanges cannot discontinue APTC due to a failure to file and reconcile (FTR) associated APTC unless direct notification is first sent to the tax filer 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 § 155.305.

We proposed to amend § 155.305(f)(4) by removing the direct notification requirement in paragraph (f)(4)(ii) and revising the remaining paragraph (f)(4) to move the content in paragraph (f)(4)(i) into paragraph (f)(4).

We are finalizing this policy as proposed.

Comment: Nearly all commenters on this issue expressed concern that relying on a notice that is not explicit to inform consumers that APTC eligibility may be discontinued—without giving consumers the specific reason and clearly instructing them how to correct the issue—is insufficient to ensure those wishing to continue their eligibility have the necessary information to do so. A few commenters stated that FFE [43] notices are often difficult for consumers to understand, and consumers often bring their notices to assisters for help understanding them. One commenter stated that this confusion can be compounded for non-English or non-Spanish speakers, who often are unable to understand notices because they are unable to read them and may not take the notices to an enrollment assister or otherwise have the notice translated in time to take the appropriate action. One commenter recommended Exchanges send multiple notices regarding failure to file and reconcile to affected consumers and tax filers.

Response: We recognize that describing complex information about eligibility for APTC to consumers involves a complicated balance between providing complete and accurate information, and being clear and concise enough that the consumer is likely to read and understand the information. Understanding this information can be especially challenging for non-English speakers. Exchanges must notify consumers when they make eligibility determinations based on FTR, but rules on the disclosure of Federal tax information (FTI) present significant challenges in communicating with this population. Historically, all communications regarding FFE applicants and enrollees are addressed to the household contact, who in most cases is the tax filer for the applicants on the relevant application. Internal Revenue Service (IRS) rules generally prohibit the disclosure of FTI to anyone other than the tax filer, and FTI includes all information from a tax return, including information as to whether a tax return has been filed with IRS. Also considered FTI is any list that is generated based only on information that is FTI itself. For example, a list of consumers who have not filed a tax return is considered FTI. The FFE's current noticing infrastructure does not

[43] All Exchanges using the Federal eligibility and enrollment platform, including SBE–FPs, take the same approach to handling FTR associated APTC. Therefore, in this section, the term ''FFE'' describes all Exchanges using the Federal eligibility and enrollment platform.

have FTI privacy safeguards built into its system to send notices to tax filers (as distinct from the household contact), to store notices in a manner compliant with required protections for FTI, or to establish user permissions for approved Exchange and Exchange contractor personnel only to access these notices for operationally necessary purposes, such as Call Center support, casework, or appeals.

To avoid unauthorized disclosure of FTI to individuals who are not the relevant tax filer, the FFE sends notices to FTR and non-FTR consumers that contain language regarding FTR, but also language that is broad enough to apply to all consumers who receive them; these notices are referred to as ''combined notices.'' For example, the FFE sends the same Marketplace Open Enrollment Notice to three groups of consumers at risk for APTC discontinuation in the upcoming coverage year: Those flagged as FTR, those for whom the FFE has received updated income information that suggests the consumers may have income too high to qualify for APTC, and those who did not permit the Exchange to check IRS data. Because the combined notices apply and are sent to some consumers who are currently unaffected by FTR, and not exclusively to individuals who are affected by FTR, these notices are not considered FTI under IRS rules and are able to be sent using the standard FFE notice functionality.

To supplement the combined notice, in November 2017, the FFE also mailed warning notices that complied with FTI rules to tax filers on whose behalf APTC was being paid but for whom the FFE had information the tax filer had not met the requirement to file and reconcile. These notices, which we refer to as ''direct notices,'' urged the tax filers to file and reconcile to avoid losing APTC starting in January 2018. To comply with FTI requirements, the direct notices were not generated by the FFE itself; rather, data was securely sent to an FTI-compliant print contractor for printing and mailing. In order to be FTI-compliant—including being accessible only to the tax filer—direct notices are not available through the online Exchange account for the application.

We intend for the FFE to continue sending two notices in advance of open enrollment where the Exchange has information that the tax filer on whose behalf APTC is being paid has failed to meet the requirement to file and reconcile: (1) A combined notice provided according to the communication preference set for the household contact (electronic or via U.S. mail) that will be available in consumers' online accounts and to the Exchange call center; and (2) a direct notice sent via U.S. mail to the tax filer that is not available electronically in the household's online account or to the Exchange call center, in order to protect FTI. The direct notice serves to unambiguously explain that the tax filer has been identified as having failed to meet the requirement to file and reconcile and must come into compliance to avoid termination of APTC. In 2018, the FFE will also send a combined notice and a direct notice in connection with its periodic check of tax data described in § 155.330(e)(2)(iii)(B). As commenters noted, we believe sending more than one notice may increase the likelihood that consumers identify and read the notices and ultimately take action.

Comment: Many commenters disagreed with our suggestion that a success rate of 60 percent of FFE household tax filers taking appropriate action to file and reconcile in response to the combined notices was sufficient and stated that 40 percent of households failing to take appropriate action demonstrates the lack of clarity the combined noticing approach creates among consumers.

Response: We agree that there is room for improvement on a success rate of 60 percent. We foresee this success rate rising as the Exchanges mature and consumers become more familiar with the requirement to file and reconcile, and as the FFE continues pairing the combined notices with direct notices to tax filers that more explicitly address the requirement to file and reconcile.

Comment: Many commenters were concerned that our proposal to remove § 155.305(f)(4)(ii) does not comply with constitutional due process rights—stating that when determining a tax filer ineligible to continue receiving APTC, Exchanges must issue a direct individual notice that contains a statement of the intended action, reasons for the action, specific legal support for the action, an explanation of the individual's hearing rights, and rights to representation and to continued benefits. They expressed concerns about consumer confusion given that neither the FFE's combined (non-FTI) notices nor follow-up through the call center can give consumers definitive guidance on their household tax filer's current tax filing status, whether they will be redetermined ineligible for APTC for the upcoming benefit year (and why), how to correct the problem, or how to challenge a redetermination of eligibility for APTC.

Response: We recognize there are limitations with the combined notices, which are unable to be explicit; however, this approach may be the only option available to many State Exchanges whose systems (including notice functionality) were not built for FTI compliance, and for which costly and time-consuming infrastructure upgrades are infeasible in the short term. As described previously, the FFE has begun mailing FTI-compliant direct notices to tax filers that contain a statement of the intended action, reasons for the action including regulatory support for the action, and an explanation of the individual's appeal rights if APTC is discontinued. While the FFE has been able to develop this workaround to provide FTI-compliant notices directly to tax filers, SBEs may have fewer options available to them. While some SBEs may be able to contract with the FFE's print contractor or another FTI-compliant contractor, we have heard that some are required to use only in-State contractors, which can create a significant barrier if there are no FTI-compliant contractors in the State.

We agree with commenters that it is important for all Exchanges to protect consumers' due process rights. Even in the case of an Exchange that cannot arrange to send direct notices that explicitly address FTR to the tax filer and that is limited to the combined notice approach, we believe there are adequate protections for due process. First, the tax filer still has an opportunity before the Exchange redetermines eligibility to file a tax return (or an amended tax return, as applicable) and reconcile APTC paid for the relevant benefit and tax year. We expect Exchanges to send appropriate notices to households affected by FTR that alert the tax filer that FTR may be the reason enrollees' eligibility for APTC is at risk. Second, for enrollees whose eligibility for APTC is terminated as a result of FTR, the enrollee will receive an updated eligibility determination notice that contains a full explanation of appeal rights. Enrollees who appeal may request to continue receiving financial assistance during the appeal, consistent with § 155.525. We believe these measures, including the option to maintain eligibility during an appeal, are consistent with due process.

Comment: Some commenters stated that tax filers have a property interest in the continued receipt of APTC for which they are eligible, and challenged our belief that the financial and operational burden for the Exchange of establishing a mechanism to notify tax filers without making an unauthorized disclosure of protected FTI would be

out of proportion with the limited need for FTI handling in Exchange operations, including generating notices. Some referenced a Federal judicial decision [44] stating that the ''public interest in assuring that health benefits will not be erroneously terminated or denied outweighs the State's competing fiscal and administrative concerns. Any inconvenience the State might suffer is out-balanced by the State's and the recipient's interest in providing health benefits to those who cannot otherwise afford them.''

One SBE supported the proposal to remove the direct notification provision in § 155.305(f)(4)(ii), citing significant implementation challenges to communicate with consumers without violating IRS's FTI security protections. It stated that current FTR processes and notifications being implemented by most Exchanges provide adequate notice to consumers.

Response: HHS is committed to ensuring consumers eligible for APTC maintain that important benefit; however, we also believe that ensuring consumers are not receiving APTC improperly is necessary for program integrity. Additionally, it is important to reduce burden on Exchanges, which have varying capacities. Establishing a mechanism through which to notify tax filers without making an unauthorized disclosure of protected FTI is a heavy undertaking for an Exchange if its notification system was not originally designed with that capability in mind. For the FFE, it would involve not only changes to its notice generation and storage infrastructure, including enhancements to segregate and secure FTI data, but also substantial modification to its entire account creation framework.[45] For a number of SBEs, upgrading their systems to be FTI compliant represents an undertaking that may be infeasible to implement in the short term. SBEs may also be unable to take the FFE's dual noticing approach because of limited print contracting options, as discussed above. The FFE plans to continue sending direct notices to tax filers to supplement the combined notices; we encourage SBEs to take a similar noticing approach, where feasible. We are available to provide technical assistance, as needed.

Comment: A few commenters recommended more research be done prior to the rule change. One commenter suggested we learn more about why taxes are not being filed in a timely way, suggesting there may be many reasons for non-compliance, and that this additional understanding could inform appropriate Exchange and IRS policies. Other commenters recommended we retain the current rule until we understand the impact of the new direct notice mailed in November 2017 to FFE enrollee tax filers affected by FTR. They suggested that, following the open enrollment period for 2018, we should assess whether there was an increase in the proportion of tax filers who took the necessary action to file their tax return and reconcile APTC, and a decrease in consumer confusion (for example, evidenced by the number of FTR-related call center questions), and consider whether any change is due to the cumulative impact of the two notices before finalizing any regulatory changes related to FTR procedures.

Response: We agree that gathering data on the effectiveness of FTR notices is a worthwhile endeavor, and we look forward to analyzing the numbers as suggested by the commenter, now that the open enrollment period for 2018 coverage is closed, to determine if recent messaging increased compliance and reduced the discontinuation of APTC as a result of FTR. However, we believe this regulatory change must be implemented in the short term in the interest of program integrity and to reduce burden on Exchanges.

Comment: A few commenters discussed the limitations when the household tax filer (to whom the FFE sent the direct notice in November 2017) does not reside with the household contact on the application (to whom the FFE sent the combined Marketplace Open Enrollment Notice in October 2017), which could hinder the affected individual's ability to understand the totality of the circumstances, and disagreed with our assumption that the household contact is likely to share the combined notice with the tax filer, since not all household contacts and tax filers on an application can readily and easily communicate with one another, including during medical or other emergency situations, death, separation or divorce, domestic abuse, or spousal abandonment. One commenter suggested that the combined notice sent to the household contact explain that the specific reason for the potential discontinuation of APTC will be contained in the direct notice to the tax filer. This commenter further suggested that the mailing addresses be verified against the United States Postal Service National Change of Address Database to help ensure deliverability, and that the envelopes be conspicuous to signify their importance (for example, red in color).

Response: We recognize there are household circumstances in which the tax filer and the household contact on the application do not live together. However, our data show that for 2017 and 2018 applications for which any amount of APTC was paid, 99.8 percent of household contacts listed on the application were also the tax filer. We agree that adding language to the combined notice pointing to the direct notice for additional specifics may help increase the likelihood that the tax filer fully understands the risk to continued APTC eligibility for enrollees in the household, and we may explore this approach through discussions with IRS regarding any potential FTI concerns. The FTI-compliant print contractor used by the FFE in November 2017 does verify addresses against the USPS National Change of Address Database, and we acknowledge that making envelopes more conspicuous could help ensure FTR notices are opened and read by consumers.

When consumers submit an FFE application, the filer of the application must agree to a statement that he or she has obtained consent for all people listed on the application for their information to be used for eligibility determination purposes, including verifying this information using the Exchange's trusted electronic data sources. In addition, following application submission and when selecting a plan and choosing the amount of APTC to apply to the monthly premium, the tax filer is required to agree to a statement that he or she must file a tax return for the year during which APTC is paid on his or her behalf (or on behalf of his or her spouse) and to reconcile those payments with IRS. The filer of the application specifies the contact person for Exchange communications (the household contact), as well as the method of communication they prefer—either electronic or via U.S. mail to the address they enter on the application. Because this household contact is designated as the point of contact for the enrollee(s) on the application, we

[44] *Rodriguez by and through Corella* v. *Chen*, 985 F.Supp. 1189 (D. Ariz. 1996).

[45] The FFE's current workaround of sending print-only FTI notices directly to tax filers is being performed outside of the FFE's standard notice processes, which allow household contacts to be notified according to their communication preferences (U.S. mail or electronic) and provides availability of all notices in consumers' online accounts. At a minimum, enhancements to the FFE's identity proofing requirements for all FFE accounts would be required in order to prevent disclosure of FTI information to anyone except the tax filer. Further, the call center's identity proofing practices and data systems would need to be enhanced to safeguard the information to an FTI standard, in order to continue assisting consumers with the application and enrollment process.

believe it is reasonable to assume he or she intends to receive communications about enrollees' eligibility for and enrollment in health coverage through the Exchange. Further, as this designated point of contact for Exchange enrollees, we believe this household contact would likely read these communications, and if their content discussed risk for financial assistance loss, share with the tax filer in the rare case that he or she is not the tax filer. We further believe it is reasonable to assume that the tax filer—if not the household contact—would be in contact with the Exchange enrollees for whom he or she is responsible with respect to tax filing, managing communications related to health coverage through the Exchange, or both.

We are finalizing these provisions as proposed, but remain committed to improving the clarity and effectiveness of the FTR notification process in circumstances where the Exchange has information that the tax filer has failed to file and reconcile.

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

i. Income Inconsistencies (§ 155.320(c))

Section § 155.320(c)(3)(iii) sets forth the verification process for increases in household income. Generally, if income data from our electronic data sources indicate a tax filer's attested projected annual income is *more than* the income amount represented by income data returned by the IRS and the SSA and current income data sources, § 155.320(c)(3)(iii) requires the Exchange to accept the attestation without further verification. Currently, Exchanges generally are not permitted to create inconsistencies (data matching issues) for consumers when the consumer's attested income is greater than the amount represented by income data returned by IRS and the SSA and current income data sources.

We proposed to revise § 155.320(c)(3)(iii) to specify that the Exchange will generate annual income inconsistencies in certain circumstances when a tax filer's attested projected annual income is *greater than* the income amount represented by income data returned by IRS and the SSA and current income data sources. Current regulations generally require the Exchange to accept a consumer's attestation to projected annual household income when the attestation reflects a higher income than what is indicated in data from the IRS and Social Security Administration. This approach makes sense from a program integrity perspective when both the attestation and data from trusted data sources are over 100 percent Federal poverty level (FPL), since an attestation that is higher than data from trusted data sources in that situation would reflect a lower APTC than would be provided if the information from trusted data were used instead.

However, where electronic data sources reflect income under 100 percent FPL and a consumer attests to income between 100 percent FPL and 400 percent FPL, where the attested income exceeds the income reflected in trusted data sources by more than some reasonable threshold, we believe it would be reasonable to request additional documentation to protect against overpayment of APTC, since the consumer's attested income could make him or her eligible for APTC that would not be available using income data from electronic data sources. Accordingly, we proposed to add new paragraphs (c)(3)(iii)(D) and (E), and to modify paragraphs (c)(3)(vi)(C), (D), (F), and (G), to specify that the Exchange will follow the procedures in § 155.315(f)(1) through (4) to create an annual income data matching issue for consumers if: (1) The consumer attested to projected annual income between 100 percent and 400 percent of the FPL; (2) the Exchange has data from IRS and SSA that indicates income is below 100 percent FPL; (3) the Exchange has not assessed or determined the consumer to have income within the Medicaid or CHIP eligibility standard; and (4) the consumer's attested projected annual income exceeds the income reflected in the data available from electronic data sources by a reasonable threshold established by the Exchange and approved by HHS. We proposed that a reasonable threshold must not be less than 10 percent, and can also include a threshold dollar amount. In accordance with the existing process in § 155.315(f)(1) through (4), if the applicant fails to provide documentation verifying their income attestation, the Exchange would redetermine the applicant's eligibility for APTC and CSRs based on available IRS and SSA data, which under this proposal would typically result in discontinuing APTC and CSR as required in paragraph (c)(3)(vi)(G). The adjustment and notification process would work in a manner consistent with other inconsistency adjustments laid out in paragraph (c)(3)(vi)(F).

We proposed to allow the Exchange to set the threshold for setting a data matching issue similar to § 155.320(c)(3)(vi). We proposed that a reasonable threshold should take into account that consumers with incomes near 100 percent FPL have a smaller margin for error in dollar terms. Therefore, a reasonable threshold might also include a fixed dollar amount in addition to a percentage threshold.

We are finalizing this policy as proposed, with two changes. First, after considering the intended purpose of this new program integrity measure, we have decided to add additional regulatory language to § 155.320(c)(3)(iii)(D) that exempts from this additional verification check non-citizen applicants who are lawfully present and ineligible for Medicaid by reason of immigration status.[46] These applicants do not have the same incentive to inflate their reported household income to qualify for APTC, since they are also able to qualify for APTC with a household income under 100 percent FPL. Additionally, if these applicants inflate their income, they will receive less APTC than they are eligible for, and, therefore, performing the additional verification check is not necessary to prevent overpayment of APTC. Second, we also removed the proposed regulatory language that clarified that non-citizens who attested to projected income under 100 percent FPL are not subject to this verification, because the policy only applies to consumers who attested to projected annual income between 100 percent and 400 percent of the FPL, and therefore would not apply to any applicant (either citizen or lawfully present non-citizen), making this clarifying language unnecessary.

At § 155.320(c)(3)(vi)(D), we proposed to make changes to provide consistency with changes finalized in the 2017 Payment Notice regarding the threshold for the generation of annual income data matching issues for decreases in annual household income. This proposed change would specify that the 10 percent threshold standard no longer applies to cases when a tax filer's attested projected income is less than all data sources, or when no electronic data sources are available. Instead, an Exchange would use the reasonable threshold established in accordance with § 155.320(c)(3)(vi). We are finalizing this change as proposed.

In the proposed rule, we also noted our interest in providing further guidance on the appropriate thresholds for the generation of data matching issues generally. We intend to reconsider and provide further guidance

[46] FFEs generally verify citizenship/immigration status prior to verifying income. If an applicant's immigration status has not been verified when the income verification would occur, they would not be exempted from this additional verification check.

on these thresholds in the near future, and in anticipation of that effort, we sought comment on the appropriate thresholds to use at various income levels and in various circumstances. In particular, we welcomed data and evidence on this issue.

We intend to address this issue as part of broader rulemaking and guidance on a number of related program integrity issues, including further examination of our processes for denying eligibility for subsidies for individuals who have failed to reconcile APTC on their Federal income tax return, Exchange processes for matching enrollment data with Medicare and Medicaid in order to address consumers who may be enrolled in duplicative coverage, and our rules around recalculation of eligibility for APTC following a mid-year change in eligibility. In anticipation of these actions, we sought comment generally on these and other program integrity topics.

Comment: Several SBEs expressed concerns over the cost and time needed to implement the change in their IT systems to accommodate the proposed new verification process. They also stated that State Exchanges should have the flexibility to not conduct this verification. One commented that there is no incentive for applicants to inflate their income in a State that expanded Medicaid.

Response: HHS understands that Exchanges may need additional time to implement this proposal in order to update their information technology systems to incorporate new logic. However, we believe this is a critical program integrity measure. This process is primarily intended as a program integrity safeguard with respect to States that did not expand Medicaid. However the verification check could also help identify some applicants who inaccurately attested to too high an income amount and were therefore inaccurately determined or assessed not to be eligible for Medicaid. This check could help applicants identify potential eligibility through their State Medicaid program and encourage them to disenroll from their Exchange plan.

Comment: Many commenters were concerned that this new verification process would disadvantage households with lower household incomes, since these households often have income amounts that fluctuate more regularly and by a larger percentage margin than higher income households. Additionally, many commenters expressed concern that low-income consumers have difficulty in providing documentation to resolve their annual income data matching issues and that this proposal would exacerbate that problem. Commenters also suggested that HHS should more strongly consider providing notice to applicants that they should update their application with any income changes, rather than creating annual income data matching issues for this population.

Response: We recognize that households with lower income might experience higher relative levels of variance in their income from year-to-year. This policy recognizes the need to have a reasonable threshold for income discrepancies to allow for normal variations in income, which may include a dollar threshold amount. HHS believes that the alternate verification process has improved significantly since the program has launched. The calculator used by HHS to calculate income submitted by applicants has been specifically modified to handle instances where income fluctuates, or is seasonal in nature. We released a consumer guide to households to help them provide the correct documentation to verify their income in the event of an inconsistency. We also released a worksheet for households to help them verify their attested income amount. HHS supports encouraging applicants to continue to update their income throughout the year, as needed, through notices and other appropriate consumer outreach and educational materials. We are also exploring strategies to promote more timely and accurate reporting of changes in circumstances by consumers.

Comment: Several commenters expressed concern that HHS did not provide evidence or data that this issue was sufficiently problematic to require a change in the regulation.

Response: HHS acknowledges that it does not have firm data on the number of applicants that might be inflating their income to gain APTC, but believes that it is reasonable to design an appropriate program integrity check, particularly when incentives may exist for applicants to do so.

Comment: Commenters also suggested that instead of generating annual income data matching issues for this population, HHS should instead closely assess the eligibility for loss of MEC special enrollment periods involving the loss of Medicaid.

Response: HHS currently monitors and verifies eligibility for special enrollment periods due to loss of MEC, including the loss of eligibility for Medicaid/CHIP.

Comment: Several commenters expressed concern that applicants who could not successfully verify their income in States that have not expanded Medicaid would be left with no practical ability to purchase health insurance.

Response: HHS understands the concern regarding these consumers and believes the alternate verification process will be able to verify income information for applicants who accurately reported their income information. Applicants who inflate their income to gain access to APTC would not be able to produce documentation required to verify their income attestation, which would properly result in the inconsistency process under the proposed policy determining these applicants ineligible for APTC. This proposal is designed to provide a program integrity check that helps protect taxpayers from the overpayment of APTC.

Comment: One commenter stated that the proposal would not result in the Treasury recouping excess APTC paid for applicants who inflated their income to gain access to APTC because applicants with household income under 100 percent FPL are exempted from repaying APTC through the reconciliation process at tax time under current regulations.

Response: We view this policy as a critical program integrity measure, notwithstanding any liability that the tax filer may have when filing income taxes and reconciling APTC paid during the inconsistency period. As observed by the U.S. Government Accountability Office, without proper procedures for verifying incomes and family sizes, the risk of providing APTC on behalf of individuals who do not meet the minimum income eligibility requirements—including those who may purposefully misstate their incomes in order to gain access for APTC—is increased.[47] Particularly to the extent funds paid for APTC cannot be recouped through the tax reconciliation process, it is important to ensure these funds are not paid out inappropriately in the first instance.

Comment: One commenter suggested that the proposed policy could result in increased churn between Medicaid and coverage through the Exchange for

[47] U.S. Government Accountability Office, Improper Payments: Improvements Needed in CMS and IRS Controls over Health Insurance Premium Tax Credit (July 2017), available at *https://www.gao.gov/assets/690/685777.pdf.* See, also Office of Inspector General, U.S. Department of Health and Human Services, Not All of the Federally Facilitated Marketplace's Internal Controls Were Effective in Ensuring That Individuals Were Properly Determined Eligible for Qualified Health Plans and Insurance Affordability Programs (August 2015), available at *https://oig.hhs.gov/oas/reports/region9/91401011.pdf* (concluding that HHS should improve its processes for verifying income eligibility for insurance affordability programs).

consumers whose household income fluctuates near the 100 percent FPL level if they are unable to verify their income for APTC eligibility. The commenter was concerned that in States that expanded Medicaid, the applicants that lost their APTC would not necessarily know that their income may make them eligible for Medicaid.

Response: HHS acknowledges this concern and will explore ways to provide helpful information in any notice provided to these applicants that lose APTC because of their inability to verify their income and may be eligible for Medicaid.

We are finalizing the changes as proposed.

ii. Verification of Eligibility for Employer Sponsored Coverage (§ 155.320(d))

An employee, or a member of the employee's family, who is eligible to enroll in qualifying coverage in an eligible employer-sponsored plan is not eligible for the PTC unless the plan's coverage for the employee is either unaffordable, as defined in section 36B(c)(2)(C)(i)(II) of the Code, or does not provide minimum value, as defined in section 36B(c)(2)(C)(ii) of the Code. An employee (or member of the employee's family) also is not eligible if he or she actually enrolls in the employer-sponsored plan, even if the plan is not affordable or fails to provide minimum value.

When an individual submits a request for an eligibility determination for insurance affordability programs, including as part of the eligibility verification process for APTC and CSRs, § 155.320(d) requires the Exchange to verify whether the applicant reasonably expects to be enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested. Paragraph (d)(2) of § 155.320 describes the data sources an Exchange must use to perform verification. Paragraph (d)(2)(i) requires an Exchange to obtain data from any electronic data sources that are available to the Exchange and which have been approved by HHS based on evidence showing that such data sources are sufficiently current, accurate, and minimize administrative burden. Paragraph (d)(2)(ii) requires that the Exchange also obtain available data based on Federal employment through HHS, and paragraph (d)(2)(iii) requires the Exchange to obtain available data from the SHOP that corresponds to the State in which the Exchange is operating. Under § 155.320(d)(4), if an Exchange is unable to fulfill the requirement to connect to the data sources set forth in (d)(2), the Exchange is required to conduct sampling as described under paragraph (d)(4)(i), or—for benefit years 2016 and 2017—it may conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii).

We proposed to amend § 155.320(d)(4) to allow an Exchange to conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii), for benefit years through 2019. When we introduced this option for benefit years 2016 and 2017, we received comments that encouraged us to make this option permanent. However, at the time we stated that we believed the alternative process should be used as an interim measure to gather information about the verification process as Exchanges improve their long-term verification programs.[48] When we first introduced this option, we also stated that we believed the temporary option would provide Exchanges with needed flexibility as verification processes are refined and employer databases compiled, to improve long-term verification programs. We noted in the proposed rule that while Exchanges have since gained greater access to data and explored approaches to sampling, challenges remain. To reduce regulatory burdens on Exchanges while they address remaining hurdles to developing a long-term approach to verification, we stated we believe the option to use an alternative process instead of sampling should be extended through plan year 2019.

After the option to use an alternate process for benefit years 2016 or 2017 was finalized, HHS investigated the feasibility of connecting to a comprehensive database of information on employer-sponsored coverage that could be used by all Exchanges to fulfill verification requirements under § 155.320(d)(2)(i). Such a database would be most useful and cost-effective if it contained information on employer-sponsored coverage from as many non-Federal and non-SHOP employers as possible. We found that a comprehensive database does not currently exist and building such a database would be a resource-intensive endeavor. In addition, employers are not required to provide information to Exchanges or HHS regarding the coverage they offer, potentially limiting the completeness of such a database.

Because of the current challenges associated with building an HHS-approved database that is sufficiently complete and accurate to satisfy requirements under paragraph (d)(2)(i), we stated we anticipate many Exchanges will fulfill verification requirements using an alternate process, as described under paragraph (d)(4). In recognition of the challenges that Exchanges may encounter with conducting sampling, as explained below, we proposed to extend the option for Exchanges to conduct an alternative process to sampling through benefit year 2019. Our hope is that Exchanges can continue to compile databases sufficient to meet verification requirements under paragraph (d)(2) and to continue to refine their approaches to sampling to meet verification requirements under paragraph (d)(4)(i).

In accordance with the requirement at paragraph (d)(4) to pursue an alternate process, the FFE conducted a pilot study that incorporated many components of sampling. The pilot was intended to assess sampling's value protecting the integrity of the attestation process regarding applicant access to and enrollment in employer-sponsored coverage. As part of this sampling pilot, employers for a small sample of enrollees receiving APTC through the FFEs were contacted by telephone, based on the employer contact information applicants provided on their Exchange applications, and asked whether specified employees were also enrolled in a qualifying employer-sponsored plan or were offered qualifying coverage in an employer-sponsored plan. Since the FFE does not have access to relevant data from employers across the 38 States for which the FFE operates Exchanges, this effort provided an attempt to collect information on each sampled employee by contacting employers' human resources personnel. The FFE found that this approach was not a cost-effective way for the FFE to fulfill verification requirements using an alternate process.

We acknowledged that sampling may be a more cost-effective option for SBEs compared to FFEs. For example, the FFE operates Exchanges for 38 States, and the volume of employers that the FFE encompasses may inherently present challenges in relying on sampling results that States may not face. Some States may collect and have access to data from employers that make verifying consumers' attestations more efficient and reliable, or may have existing channels through which they can communicate with in-State employers. Therefore, we proposed to maintain the option to use sampling as an alternate method of verification under paragraph (d)(4) to allow SBEs maximum

[48] 81 FR 12203, 12269 (March 8, 2016).

flexibility. We stated that we expect that the proposed change to paragraph (d)(4) to allow Exchanges to continue to use an HHS-approved alternative process to sampling through plan year 2019 will provide Exchanges with important flexibility to conduct the most efficient, reliable alternate method of verification as Exchanges refine their approaches to conducting sampling over time, and until data sources exist that provide an effective way to verify consumers' enrollment in or access to qualifying employer-sponsored coverage. If SBEs use an alternative process to sampling to conduct verification under paragraph (d)(4)(ii), the process must be approved by HHS. To be approved by HHS, we expect an Exchange to develop an alternate process that provides insight into whether employees provide accurate information or the Exchange effectively verifies information about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan.[49] This requires Exchanges to conduct reliable and sufficient verification, while giving them the flexibility to find the most efficient ways of doing so for their Exchange.

We noted that to the extent an Exchange believes an alternate process to verification through data sources or methods other than those described under paragraph (d) may result in a more efficient or comprehensive verification procedure, the Exchange may also, in accordance with §§ 155.315(h) and 155.320(a)(2), request HHS approval for use of an alternate process for verifying enrollment in and access to employer-sponsored coverage. We noted that HHS received support for providing flexibility for the use of alternate data sources by Exchanges in comments to the Request for Information. For example, we received comments indicating that, for some Exchanges, due to the limited number of Federal employees in their State, connecting to the database containing data on Federal employment provides little utility in Exchange verification of applicants' eligibility for employer-sponsored coverage. One commenter encouraged HHS to consider removing the regulatory requirement to connect to this database for purposes of employer-sponsored coverage verification. We have also received feedback from some Exchanges noting challenges and limitations connecting to a SHOP database. These Exchanges noted that, given the limited enrollment in SHOP in many States and that many States do not have a SHOP database with which to connect, requiring verification through SHOP imposes a technical and financial challenge for States that may not be the most efficient and cost-effective way to perform verification.

Additionally, we sought information and suggestions on ways to improve verification of whether an applicant reasonably expects to be enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested.

We are finalizing this policy as proposed.

Comment: All commenters supported the proposal to amend § 155.320(d)(4) to allow an Exchange to conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii), for benefit years through 2019. Most commenters noted the continued need to perform verification through an alternate process under paragraph (d)(4), and supported the flexibility to perform alternative methods of verification to sampling under paragraph (d)(4)(ii).

Response: We acknowledge the continuing need Exchanges may have to use an alternate verification process and the flexibility to perform an alternative verification procedure to sampling. We are finalizing this provision as proposed.

Comment: Most commenters indicated that challenges remain in performing verification through some or all of the databases described under paragraph (d)(2). One commenter questioned the value of verifying based on Federal employment data and through data based on the State's SHOP Exchange due to the low number of applicants offered eligible coverage from those sources in the relevant State. Several commenters supported the flexibility provided under § 155.315(h) for Exchanges to request HHS approval to perform verification through data sources or methods other than those specified in paragraph (d) where an Exchange believes alternate data sources or methods may result in a more efficient verification procedure for that Exchange.

Response: We agree that challenges remain to performing verification through databases described under paragraph (d)(2), and that an Exchange may believe verification through alternate data sources would be a more appropriate method of verification for their Exchange. While we believe that verification through databases described under paragraph (d)(2) remains a viable option for some Exchanges, we continue to provide Exchanges the flexibility afforded under § 155.315(h), and support Exchanges in considering this option for verification.

c. Eligibility Redetermination During a Benefit Year (§ 155.330)

We sought comment on ways to better encourage enrollees to report changes in circumstance occurring during the benefit year that may affect their eligibility for Exchange coverage or for APTC or CSRs. The FFEs currently conduct proactive outreach to enrollees through a variety of means, including emails, phone calls, and paper mail, to encourage them to return to the Exchange to update their information throughout the benefit year and during key Exchange operational efforts, such as open enrollment. The FFEs also periodically provide general information and reminders to enrollees. However, many changes in circumstance, such as changes in household income or size, remain unknown by the Exchanges until reported by the enrollee.

We are interested in hearing from stakeholders about ways to increase enrollee reporting of individual changes in circumstance within 30 days of the change in order to ensure compliance with § 155.330(b). Increasing such reporting would benefit enrollees by ensuring that they continue to be enrolled based on their current eligibility for financial assistance, and would improve program integrity.

Comment: Commenters supported finding ways to better encourage Exchange enrollees to report changes in circumstance during the benefit year so that they receive updated eligibility determinations, including with respect to any APTC they are receiving. Commenters acknowledged the benefit of timely updates to an enrollee's household income or family size as a way to help minimize any large APTC reconciliation payments due to the Federal government upon filing a Federal income tax return. Commenters also acknowledged the benefit to the program integrity of the Exchanges, so that they may continue to have updated and accurate enrollee information, as well as the benefit to the Federal government to minimize the amount of financial assistance being paid on behalf of enrollees who are not eligible (or are eligible for a lesser amount).

Commenters recommended increasing Exchange outreach efforts, through mail, email, and social media networks, to periodically remind consumers to report any life changes that may have occurred. One commenter recommended that Exchanges use more distinct envelopes when an enrollee action is required to improve the rate at

[49] 81 FR 94058, 94125 (December 22, 2016).

which these mailings are recognized, read, and acted upon. Commenters acknowledged the benefit of personal interactions as a way to encourage consumer behavior and recommended that Exchanges engage Navigators who have personal relationships with many Exchange enrollees to keep in contact with the enrollees throughout the year and remind them that they should timely report changes in circumstance to the Exchange.

Commenters recommended that Exchanges make it easier for enrollees to report changes in circumstance online. One State Exchange stated they have information about reporting changes in circumstance on the main page of their Exchange website outside of open enrollment, and that enrollees are asked about whether they need to report a change either over the phone if they call the Exchange call center, or online upon logging into their Exchange accounts.

Response: We appreciate comments received on this topic and will take them into consideration for FFE operations and possibly in future rulemaking.

d. Annual Eligibility Redetermination (§ 155.335)

We are considering the possibility of amending the length of time that individuals may authorize the Exchanges to obtain the updated tax return information for enrollees as described in § 155.335(k)(2). Currently, the Exchanges may obtain updated tax return information for a period of no more than 5 years based on a single authorization.

We sought comment on whether 5 years is an appropriate duration for this type of an authorization, or whether a shorter time period should be considered. In particular, we are contemplating whether shortening this authorization period would improve Exchange program integrity by helping to ensure that the enrollee's application at the time of re-enrollment accurately reflects his or her data collection preferences, that all sources of income that may affect his or her eligibility for APTC and cost-sharing reductions are listed on the application, and that individuals update their applications on a more regular basis to reflect other changes in circumstances that affect eligibility (such as changes in employment or marital status).

Comment: Many commenters opposed changing the length of time that individuals may authorize Exchanges to obtain their updated tax information. Many commenters agreed that 5 years is the appropriate length of time for this type of authorization, and that this period accurately balances the Exchanges' need for updated information with the consumer burden of actively authorizing Exchanges to access this information. One commenter recommended that we consider extending the authorization period past 5 years, and another recommended that Exchanges be able to access this information indefinitely. In addition, several commenters questioned how shortening this authorization window would improve Exchange program integrity.

Response: We appreciate the comments and will take them into consideration in future rulemaking.

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

a. Special Enrollment Periods (§ 155.420)

i. Plan Options Under Select Special Enrollment Periods

For many special enrollment periods, a dependent of an Exchange enrollee may newly enroll in Exchange coverage or switch Exchange plans when the dependent or another qualified individual on the Exchange application qualifies for a special enrollment period. Even though dependents may access special enrollment periods based on different qualifying events, when they qualify for a special enrollment period to newly enroll in Exchange coverage, regardless of whether it is a special enrollment period due to gaining or becoming a dependent or due to a loss of minimum essential coverage, we believe that they should be treated alike. Section 155.420(a)(4) defines the coverage changes Exchange enrollees may make when they or their dependents qualify for special enrollment periods. We proposed to modify how paragraph (a)(4)(iii) treats dependents to align more closely with paragraph (a)(4)(i) which addresses when an existing enrollee gains a new dependent. To do this, we proposed to modify paragraph (a)(4)(iii) to establish a distinction between how the rule treats existing enrollees who qualify for one of the relevant special enrollment periods themselves or when existing Exchange enrollees themselves and their dependent(s) qualify for one of the relevant special enrollment periods; and when only new dependents qualify for one of the relevant special enrollment periods and are enrolling in coverage with an existing Exchange enrollee. We proposed to establish this distinction by separating these situations into new paragraphs (a)(4)(iii)(A) and (a)(4)(iii)(B). We believe the latter situation is akin to when an enrollee adds a new dependent to their coverage, even though in this situation the dependent is qualifying for a different special enrollment period.

Proposed new paragraph (a)(4)(iii)(A) would address the coverage options available to current enrollees and dependents who qualify for a special enrollment period. As is current policy under paragraph (a)(4)(iii), paragraph (a)(4)(iii)(A) would continue to allow enrollees and their dependents who qualify for the special enrollment periods specified in paragraphs (d), other than those described in paragraphs (d)(2)(i), (d)(4), (d)(6)(i) or (ii) for becoming newly eligible for CSRs, (d)(8), (d)(9), and (d)(10) of this section, to use their special enrollment period to change to another QHP within the same level of coverage or one metal level higher or lower, if no such QHP is available, as outlined in § 156.140(b) of this subchapter.

Proposed new paragraph (a)(4)(iii)(B) would address the coverage options available when only a dependent who is not currently enrolled in Exchange coverage qualifies for a special enrollment period. We proposed to revise the policy for these qualified individuals to align with paragraph (a)(4)(i) of this section. We proposed that, if a new dependent qualifies for one of the special enrollment periods specified in paragraphs (d)(1), (d)(3), (d)(6)(iii), (d)(6)(iv), (d)(7), (d)(11), and (d)(13) of this section and an enrollee would like to add the dependent to his or her QHP at that time, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the plan's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and dependent to change to another QHP within the same level of coverage; or, if no such QHP is available, allow them to switch to a QHP one metal level lower or higher, as outlined in § 156.140(b) of this subchapter. Alternatively, the enrollee may enroll the dependent in a separate QHP at any metal level.

We believe that these modifications are needed in order to align the flexibilities available to enrollees and dependents when a dependent is newly enrolling in Exchange coverage during the benefit year due to qualifying for a special enrollment period. With this proposed change, regardless of the special enrollment period for which a dependent qualifies, an enrollee may either add the dependent to his or her existing QHP, as long as he or she continues to qualify for it, or enroll the new dependent in a separate QHP at any metal level.

In the event that both the enrollee and the new dependent qualify for special enrollment periods referenced in proposed paragraphs (a)(4)(iii)(A) and (a)(4)(iii)(B), respectively, and the enrollee wants to add this new dependent to his or her QHP, the Exchange would allow both the enrollee and dependent to switch to a new QHP at the same metal level, if available, as described in proposed paragraph (a)(4)(iii)(A).

We are finalizing this policy as proposed.

Comment: The majority of commenters supported the proposal to align plan options for a dependent of an Exchange enrollee who qualifies for a special enrollment period to newly enroll in Exchange coverage along with the existing Exchange enrollee, regardless of the special enrollment period the dependent qualifies for, thereby aligning the dependent policies in paragraphs (a)(4)(i) and (a)(4)(iii)(B). Commenters appreciated the simplification of plan option rules for enrollees who seek to newly enroll a dependent in Exchange coverage after that dependent has qualified for a special enrollment period, and stated that this simplification will benefit Exchange enrollees, as well as those providing enrollment assistance, such as Navigators, agents, and brokers, by making it easier for them to understand and explain the enrollee's enrollment options. In addition, some commenters supported aligning the plan option rules out of fairness, to ensure that all similarly situated dependents who are newly enrolling in Exchange coverage should have the same enrollment options available to them.

A few commenters supported this proposal, but also requested that changes to the plan option restrictions in paragraph (a)(4) be amended to give affected enrollees and dependents the option to enroll in a QHP at a lower level of coverage, alongside the option to enroll in either the same QHP or another QHP at the same level of coverage, as applicable. Commenters stated that this increased flexibility is especially necessary for situations where enrollees are gaining or become a new dependent, in accordance with paragraph (d)(2)(i) of this section, because changes in household composition, especially the addition of a new infant or child to a household, likely change a household's health care needs and what level of coverage is best suited to meet those needs. Other special enrollment periods included in paragraph (a)(4)(iii)(B), such as the special enrollment periods for loss of minimum essential coverage in paragraph (d)(1) of this section and for being determined ineligible for Medicaid or the Children's Health Insurance Program, may similarly change a household's health care needs if, for example, dependents had been previously enrolled in Medicaid or CHIP and are losing that coverage for the first time.

Several commenters expressed concern about the technical impact the proposed changes would have on State Exchanges, especially those States that had already been working toward implementing the plan option restrictions as finalized in the 2017 Market Stabilization Rule. States cautioned that finalizing this proposal would delay their ability to implement this policy and several States requested State flexibility with respect to this proposal.

Other commenters expressed opposition to this proposed change because it would further restrict plan options available to enrollees and dependents newly enrolling in QHP coverage. These commenters stated that imposing restrictions of individuals' choice of QHPs to enroll in after he or she qualifies for a special enrollment period contradicts the intent of special enrollment periods. One commenter stated that limiting plan options for enrollees or dependents upon qualifying for a special enrollment period is prohibited by the guaranteed issue provision of the PPACA statute. The guaranteed issue provision requires that issuers accept every individual in the State who applies for such coverage and, while issuers may restrict enrollment periods, they stated, restrictions on the type of plan the individual enrolls in is not permitted.

Response: We agree that there is a benefit to aligning the plan options available to enrollees who are adding a dependent newly enrolling in Exchange coverage through a special enrollment period. We appreciate commenters' concerns about the impact household changes may have on a family's health coverage needs, but believe that maintaining these restrictions is necessary in order to continue to avoid adverse selection. We continue to encourage enrollees to explore all available QHPs during open enrollment, and to change plans if another QHP better meets their or their family's needs.

We understand that the proposed changes may delay State Exchanges' ability to implement the plan option restrictions, especially in those States where this proposal will require a change to Exchange system functionality, and, therefore, we believe it is appropriate for States to take additional time, as needed, in order to comply with this change.

Lastly, as we noted in the 2017 Market Stabilization Rule, we considered the concerns regarding conflicts of this policy with the statute, but believe that limiting enrollees' ability to change QHPs or metal levels is consistent with the requirements in section 1311(c)(6)(C) of the PPACA directing the Secretary to require Exchanges to establish special enrollment periods as specified in section 9801 of the Code and under circumstances similar to such periods under Part D of title XVIII of the Act, as well as the Secretary's authority under section 2702(b)(3) of the PHS Act to promulgate regulations for the individual market with respect to special enrollment periods for qualifying events under section 603 of the Employee Retirement Income Security Act of 1974. Given that the PPACA itself called for one annual open enrollment period and additional enrollment opportunities only in the case of special circumstances, we believe it is reasonable to interpret the special enrollment period and guaranteed issue provisions of the PPACA in this manner.

We proposed to exclude the special enrollment period in paragraph (d)(12) for material plan or benefit display errors from paragraph (a)(4)(iii). This is because we understand that certain material plan or benefit display errors may impact an enrollees' decision to enroll in a level of coverage, in addition to his or her decision to enroll in a specific QHP. Therefore, we believe that, if an enrollee qualifies for the special enrollment period because of a material plan or benefit display error, he or she should be allowed to switch to a different QHP at any metal level that better meets his or her needs.

We are finalizing the policy as proposed.

Comment: Commenters supported the proposal to exempt from the plan option restrictions in paragraph (a)(4)(iii) the special enrollment period in paragraph (d)(12) for when a qualified individual, 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. Such a material plan error may have impacted not only the specific QHP an individual enrolled in, but also the level of coverage the individual decided to purchase. One commenter requested that we provide additional guidance regarding the types

of errors that we would consider material for purposes of being excluded from the plan option restrictions in paragraph (a)(4)(iii).

Response: We are finalizing this policy as proposed. We also clarify that, while we are finalizing an amendment to exempt this special enrollment period from the plan option restrictions in paragraph (a)(4)(iii), we are not amending the criteria for qualifying for the special enrollment period in paragraph (d)(12), which is intended for when an enrollee 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 and refer the commenter to the preamble discussion of the 2018 Payment Notice where we discuss this special enrollment period.

ii. Exception to Prior Coverage Requirement for Qualified Individuals Who Have Lived in Service Areas Where No QHP Is Offered Through an Exchange

HHS recently added a prior coverage requirement to the special enrollment period for gaining access to new QHPs as a result of a permanent move, described in § 155.420(d)(7), and the special enrollment period for gaining or becoming a dependent through marriage, described in § 155.420(d)(2)(i). Section 155.420(a)(5) specifies how a qualified individual can satisfy the prior coverage requirement. Qualified individuals can demonstrate that they had minimum essential coverage as described in 26 CFR 1.5000A–1(b) for 1 or more days during the 60 days preceding the date of the qualifying event; lived in a foreign country or in a United States territory for 1 or more days during the 60 days preceding the date of the qualifying event; or are an Indian, as defined by section 4 of the Indian Health Care Improvement Act. This prior coverage requirement encourages individuals to maintain coverage throughout the year.

However, we recognize that individuals living in a service area where no Exchange QHPs are offered may not be able to obtain affordable coverage. We believe that individuals in this situation should not later be prevented from enrolling in coverage through a special enrollment period that requires prior coverage when they were previously unable to enroll in Exchange coverage because it was unavailable or inaccessible. Therefore, we proposed to amend paragraph (a)(5) to exempt qualified individuals from the prior coverage requirement if, for at least 1 of the 60 days prior to the date of their qualifying event, they lived in a service area where there were no QHPs offered through an Exchange. Absent this change, qualified individuals who have lived for part of the benefit year in a location where no QHPs were offered through an Exchange, and, therefore, may have been unable to enroll in minimum essential coverage, would be prevented from subsequently qualifying for a special enrollment period due to a permanent move or marriage.

Additionally, we noted that the proposed amendment to paragraph (a)(5) would apply, along with the rest of the paragraph, to the individual market outside of the Exchange through the cross-reference to § 155.420(d) in § 147.104(b)(2). In this context, health insurance issuers offering coverage outside an Exchange would not be able to require qualified individuals to demonstrate prior coverage if they lived for at least 1 of the 60 days prior to their qualifying event in a service area where there were no QHPs offered through an Exchange.

We are finalizing the policy as proposed, except that we are amending the regulatory text to ensure the exception applies to individuals who lived in a service area where no QHPs were offered through an Exchange during their most recent Exchange enrollment period, regardless of whether that enrollment period was an Exchange open enrollment period or a special enrollment period. This change will address situations where no QHPs were available to an individual during their enrollment window, but later became available in the individual's service area prior to his or her marriage or move.

Comment: Commenters supported the proposal to exempt qualified individuals from the prior coverage requirement if, for at least 1 of the 60 days prior to the date of their qualifying event, they lived in a service area where there were no QHPs offered through an Exchange. Several commenters added that HHS should continue to implement procedures currently in place to verify other aspects of the applicable special enrollment period qualifying event, such as a move, within the required 60-day window. Commenters also requested, if this exception to the prior coverage requirement becomes necessary, that HHS publish a list of service areas in which no QHPs are offered through an Exchange, in part to ensure that issuers can apply the exception accurately in the off-Exchange individual market.

One commenter raised the concern that our proposed criteria for the exception, in particular that a person only have lived for 1 of the 60 days prior to their qualifying event in a service area where there were no QHPs offered through an Exchange, was not stringent enough. This commenter suggested that such a brief residency requirement could lead individuals to move to an affected service area on a transitional basis in order to avoid the prior coverage requirement. To reduce the likelihood that individuals who did not qualify would be able to take advantage of this exception, the commenter recommended that we require individuals to have been residents in a service area without QHPs for the entire 60 day period prior to their qualifying event.

Response: We will consider publishing a list of service areas in which no QHPs are offered by the Exchange, so that this exception can be applied consistently and accurately off-Exchange. In addition, we may release additional guidance if a service area is left without QHP coverage and it becomes necessary to implement this exception.

We understand concerns that individuals may seek to fraudulently claim this exception in order to avoid the prior coverage requirement, and we remain committed to promoting continuity of coverage and ensuring that only eligible consumers may access coverage through special enrollment periods. However, we believe that this exception for individuals who have lived in a service area where no QHPs are offered by the Exchange for at least 1 of the 60 days before a qualifying event or during their most recent preceding enrollment period is important, because it takes into account the potential for a service area to temporarily be without a QHP, such as in the case of a temporary QHP suppression or mid-year QHP decertification, and the need to protect individuals who may be affected by this lack of availability. Additionally, we note the need to ensure that individuals are not prevented from accessing coverage through a special enrollment period mid-year because of having lived in a service area where no QHPs were offered through the Exchange during their most recent enrollment period (open enrollment or special enrollment period) when they could have otherwise enrolled in affordable coverage, even if during the 60 days before a subsequent qualifying event a QHP is available in their service area. Therefore, we are finalizing this exception to the prior coverage requirement that currently applies to certain special enrollment periods to include consumers who lived

in a service area where no QHP was available through the Exchange during their most recent preceding enrollment period.

We also note that concerns that individuals will fraudulently claim eligibility for an exception to the prior coverage requirement are addressed in part because the FFE will continue to require document-based verification of the individual's eligibility for the special enrollment period and, in order to qualify for the special enrollment period due to a permanent move, individuals will continue to be required to meet the residency requirements for their new and former addresses, in accordance with § 155.305(a)(3) and as explained in the January 2016 *FAQs on the Marketplace Residency Requirement and the Special Enrollment Period due to a Permanent Move.*[50] Finally, we anticipate that this exception will be granted extremely rarely, which minimizes the risk that it will be used inappropriately.

iii. Effective Date Options for Special Enrollment Periods Relating To Gaining or Becoming a Dependent

Paragraph (b)(2)(i) of § 155.420 requires Exchanges to provide individuals who qualify for a special enrollment period due to gaining or becoming a dependent through birth, adoption, placement for adoption, or placement in foster care, as described in paragraph (d)(2)(i), with a retroactive coverage effective date back to the date of the qualifying event. It also gives Exchanges the option to allow these consumers to elect an effective date of the first of the month following the date of the event or following regular coverage effective dates, in accordance with paragraph (b)(1) of this section. Paragraph (b)(2)(v) addresses coverage effective date options for special enrollment periods related to gaining or becoming a dependent due to a child support or other court order, as also described in paragraph (d)(2)(i). It requires Exchanges to ensure that coverage takes effect on the date of the court order, and it permits Exchanges to allow qualified individuals to elect an effective date based on paragraph (b)(1). However, it does not provide Exchanges with the option to allow qualified individuals to elect that their coverage begin the first of the month following the date of the event.

We proposed to remove paragraph (b)(2)(v) of this section and to revise paragraph (b)(2)(i) to include the special enrollment period for a court order and redesignate current paragraph (b)(2)(vi) as paragraph (b)(2)(v). These revisions would align the coverage effective dates for all special enrollment periods based on gaining or becoming a dependent, with the exception of gaining or becoming a dependent through marriage. Aligning coverage effective date options ensures that Exchanges provide qualified individuals in similar situations with the same flexibility with regard to coverage effective dates.

We also proposed to modify paragraph (b)(2)(i) so that, in addition to requiring an Exchange to ensure that coverage is effective retroactive to the date of the qualifying event, it may permit the qualified individual or enrollee to elect a coverage effective date of the first of the month following plan selection, rather than the first of the month following the qualifying event, as currently written, or following regular coverage effective dates, in accordance with paragraph (b)(1) of this section. This amendment would streamline Exchange operations and align this coverage effective date option with the accelerated prospective coverage effective date rule as it applies to other special enrollment periods, including the special enrollment period for gaining or becoming a dependent through marriage, as described in (b)(2)(ii) of this section.

Therefore, individuals who qualify for a special enrollment period due to gaining or becoming a dependent through birth, adoption, placement for adoption, or placement in foster care, or through a child support or other court order, will be able to elect from the same alternate coverage effective date options, if offered by their Exchange.

We are finalizing this policy as proposed.

Comment: Commenters supported the proposal to align the coverage effective date options for those who gain or become a dependent through birth, adoption, or foster care placement with those who gain or become a dependent through a child support or other court order. Commenters agreed that aligning special enrollment period coverage effective date options for most situations where individuals are gaining or becoming a dependent would result in a simpler rule and more intuitive operational processes, both reducing administrative burden on issuers and on agents and brokers and helping individuals better understand their coverage effective date options. One commenter opposed this proposal due to concerns that it would reduce State flexibility, could increase burden on Exchanges due to costs associated with updating their systems to reflect new effective date options in States that offer this optional alternate coverage effective date option to consumers, and limit individuals' access to retroactive coverage options.

Response: We agree that these changes will promote the goals of providing the same alternate coverage effective date options to consumers who qualify for a special enrollment period due to gaining or becoming a dependent through a birth, adoption, foster care placement, or court order, and of streamlining Exchange operations by revising the ''first of the month'' coverage effective date option so that it can be operationalized in the same way for all special enrollment periods for which it is an option. We note that this proposal does not remove or alter the requirement at § 155.420(b)(2) that Exchanges ensure that coverage is effective retroactive to the date of the qualifying event for consumers who qualify for a special enrollment period due to gaining or becoming a dependent through a birth, adoption, foster care placement, or court order.

We acknowledge that allowing Exchanges to permit individuals to elect that their coverage take effect on the first of the month following plan selection instead of on the first of the month after the date of their qualifying event will mean that consumers only have one option for their coverage to take effect retroactively—back to the date of their qualifying event—whereas prior to the change, they could request that coverage take effect retroactive to the first of the month after their qualifying event if their Exchange allowed this option. However, we also note that the proposed change adds an accelerated prospective option that is not currently available to these consumers.

Additionally, we believe that, while some Exchanges may need to make system updates based on this change, they will have the flexibility that they need in order to manage the potential impact because Exchanges are not required to offer these alternate coverage effective date options and may delay implementation if necessary. Finally, the alignment of this effective date option with the ''first of the month'' effective date that also applies to other types of special enrollment periods (in particular the special enrollment period due to gaining or becoming a dependent through a marriage), will also likely generate efficiencies for Exchanges in the long term.

[50] Available at *https://www.regtap.info/uploads/library/ENR_FAQ_ResidencyPermanentMove_SEP_5CR_011916.pdf.*

iv. Loss of Coverage Special Enrollment Period (§ 155.420(d)(1)(iii))

Section 155.420(d)(1) establishes a special enrollment period for qualified individuals who lose certain types of coverage, including minimum essential coverage. As described in paragraph (d)(1)(iii), qualified individuals who lose certain types of Medicaid pregnancy-related coverage not considered minimum essential coverage may also qualify for this special enrollment period. This is to ensure that women losing eligibility for coverage of pregnancy-related services that often meet their primary and specialty health care needs are not left without the option to enroll in a QHP through an Exchange after they lose access to those services.

We proposed to revise paragraph (d)(1)(iii) to include women who lose access to health care services that they were receiving through CHIP coverage for their unborn child. While CHIP coverage for unborn children, provided based on the definition of a child described in 42 CFR 457.10, is considered minimum essential coverage for the unborn child, it is not considered minimum essential coverage for the pregnant woman. Nonetheless, these pregnant women may receive a set of health services comparable to those available to women enrolled in Medicaid pregnancy-related coverage. For this reason, pregnant women who have received prenatal care as part of CHIP coverage for their unborn child may apply and be determined eligible for a hardship exemption from the FFEs so that they are not required to also maintain minimum essential coverage during that time.

The proposed revision to paragraph (d)(1)(iii) would provide a pathway to coverage for new mothers who lose access to health care services provided through unborn child CHIP coverage following the birth of their child, and who are otherwise eligible to enroll in a QHP through the Exchange. Under paragraph (c)(2) of this section, these qualified individuals would have up to 60 days before or after the loss of access to CHIP unborn child coverage to qualify for the loss of coverage special enrollment period and enroll in a QHP. If they select a plan prior to their loss of CHIP unborn child coverage, their Exchange coverage would begin as soon as the first day of the month following the loss of coverage. If they select a plan after the loss of CHIP unborn child coverage, their Exchange coverage would begin either the first of the following month or following regular, prospective coverage effective dates at the option of the Exchange, as provided under paragraph (b)(2)(iv). We believe that this revision is needed to ensure a pathway to coverage for women in the 17 States that offer unborn child CHIP coverage, so that they may maintain access to continuous coverage after the birth of their child.

We are finalizing this policy as proposed.

Comment: We received overwhelming support for this proposal; commenters did not raise any concerns, and noted that it would help streamline Exchange operations and ensure that women losing access to CHIP coverage for their unborn child are able to maintain continuous coverage.

Response: We are finalizing this provision as proposed.

iv. Technical Amendment (§ 155.420(d)(10)(i))

We proposed to make a technical amendment to update the cross reference to 26 CFR 1.36B–2T in § 155.420(d)(10)(i), regarding the special enrollment period for victims of domestic abuse or spousal abandonment. The temporary regulation under section 36B of the Code originally cited has now been finalized without change to the definition cited in this special enrollment period. This technical correction would not alter the parameters of this special enrollment period.

Commenters supported this proposal; we are finalizing this change as proposed.

b. Effective Dates for Terminations (§ 155.430)

Section 155.430 specifies the termination dates for Exchange enrollees. Paragraph (d)(1)(i) of § 155.430 defines ''reasonable notice'' as at least 14 days before the requested effective date of termination. Paragraph (d)(2) sets forth three possible effective dates for enrollee-initiated terminations made in accordance with paragraph (b)(1): (1) The termination date specified by the enrollee, if the enrollee provides reasonable notice; (2) 14 days after the termination is requested by the enrollee, if the enrollee does not provide reasonable notice; or (3) on a date on or after the date on which the termination is requested by the enrollee, if the enrollee's QHP issuer agrees to effectuate termination in fewer than 14 days, and the enrollee requests an earlier termination effective date. Further, current paragraph (d)(2)(iv) sets the QHP termination effective date for enrollees newly eligible for Medicaid, CHIP, or the Basic Health Program (BHP) as the day before the individual is determined eligible for Medicaid, CHIP, or BHP.

We proposed to remove paragraphs (d)(1)(i) and (d)(2)(i) through (d)(2)(iii) to align the effective dates for all enrollee-initiated terminations on the date on which the termination is requested by the enrollee or on another prospective date selected by the enrollee. We also proposed removing existing paragraph (d)(2)(iv), which states that the QHP termination date for an enrollee newly determined eligible for Medicaid, CHIP or a BHP is the date before the Medicaid, CHIP, or BHP eligibility determination. We invited comment from Exchanges, issuers, and other stakeholders on any burdens these rule changes may impose, as well as whether we should make the changes at the option of the Exchange or the issuer.

We are not finalizing this policy as proposed. Rather, we are restructuring paragraph (d)(2) to improve its readability, and, in response to comments from Exchanges responding to our solicitation of comments, providing additional flexibility to allow Exchanges to retain the current policy or operate under the proposed policy.

Comment: Supporters of our proposal to eliminate the ''reasonable notice'' requirement referenced the more streamlined and straightforward approach to terminations for consumers and its ability to reduce duplicate or overlapping coverage when enrollees obtain other coverage. Many supporters cited challenges consumers face transitioning into Medicare and stated that being able to choose the date of their QHP termination would alleviate the need to reach out to the Exchange multiple times to ensure the proper termination date to avoid having dual coverage.

Response: We agree that allowing enrollees to terminate their coverage immediately or on a future date of their choosing will provide consumers with greater control over ending their QHP coverage and will help minimize or eliminate overlaps in coverage, for example, when aging into Medicare. Such flexibility will also allow Exchanges to send termination transactions to issuers that do not need subsequent adjustment, reducing the need for casework or direct consumer contact with issuers to request termination dates to effectuate in less than 14 days.

Comment: Some commenters requested that we provide flexibility in the implementation of this rule, citing technical and operational challenges with premium proration, in addition to the common consumer desire to terminate plans at the end of the month.

Response: We acknowledge that not all Exchanges have the same system capabilities, and are providing Exchanges flexibility to implement this change at their discretion.

Comment: Several commenters opposed the rule, stating that 14 days is a reasonable industry practice for issuers, while others expressed concerns that same-day terminations are not feasible for issuer processing, due to the timing of Exchange-sent 834 transactions. Some urged HHS to work with issuers to determine a more realistic timeframe—ranging from next-day to 5 days—and implement a default end-of-month termination effective date. One commenter discussed the importance of coordination between issuers and Exchanges to synchronize enrollment and termination effective dates to reduce adverse downstream effects on payment reconciliation processes.

Response: Issuers already process a significant number of same-day terminations when removing less than the whole enrollment group from QHP coverage, and they have reported no difficulties in doing so. While we expect the vast majority of enrollees will want their coverage to end at the end of month, this option for a more precise termination date is necessary for consumers because retroactive terminations are only available in very limited circumstances.

Comment: One commenter urged us to allow issuers to transmit 834 files to the Exchange with consumer-initiated terminations, stating that most consumers notify their issuers first when terminating coverage.

Response: We recognize that many enrollees reach out to their issuers to initiate terminations. However, terminations must be triggered through the Exchange so enrollees remaining on the application can receive an updated eligibility determination.

Comment: Supporters of the proposal to remove the current Medicaid/CHIP/BHP termination rule—which allows for retroactive QHP terminations based on new Medicaid/CHIP/BHP eligibility determinations—described the current rule as a source of confusion for issuers, States, Exchanges and consumers, and noted challenges coordinating with State Medicaid agencies, as well as the volume of complex casework the rule currently triggers. One commenter recommended that HHS permit retroactive QHP terminations if the Medicaid, CHIP or BHP determination was less than 30 days in the past because it is more difficult for plans to reverse claims after 30 days.

A few commenters encouraged flexibility to maintain existing policy and business operations, and others encouraged HHS to allow States to determine how the change would impact their populations, given their Medicaid eligibility processing times, as well as their ability to reach and inform consumers about their need to take action.

Response: We agree that the current Medicaid/CHIP/BHP rule causes unnecessary confusion, given that we do not provide QHP termination dates according to eligibility for other forms of coverage, such as Medicare or employer-sponsored coverage. We also recognize that eligibility determinations conducted through the State Medicaid agency, instead of the Exchange, can result in challenges coordinating effective dates through the State agency, the Exchange, and its issuers; and can result in consumer complaints and subsequent casework. We recognize issuer challenges with retroactive terminations and appreciate willingness to process limited retroactive terminations. However, because we recognize that Exchanges' coordination with their Medicaid and CHIP programs varies, we are providing Exchanges flexibility to implement this change at their discretion.

Comment: Most commenters who opposed the proposal to remove the Medicaid/CHIP/BHP rule cited adverse consumer impact, and were primarily concerned about placing the burden to terminate QHP coverage on the Medicaid/CHIP/BHP enrollee who may not understand the need to terminate. One commenter stated it was important for QHP enrollees to continue to be able to recoup premium payments made when in fact eligible for Medicaid due to Medicaid's 90-day retroactive eligibility rules. Others stated that the QHP should terminate automatically with Medicaid eligibility.

Response: We recognize there may be some consumer impacts with the implementation of this rule. We also recognize that the removal of this rule may limit enrollees' ability to retroactively terminate QHP coverage when it overlaps with Medicaid/CHIP/BHP coverage, which could result in consumers being unable to recoup premiums paid for periods when the enrollee was enrolled in QHP coverage through the Exchange and gains retroactive eligibility for Medicaid/CHIP/BHP. However, these types of retroactive terminations can lead to major challenges for consumers as Medicaid/CHIP/BHP providers may not cover claims reversed by the QHP—leading to unexpected out-of-pocket costs for consumers. Finally, we agree that automatic transition from QHP coverage to Medicaid/CHIP/BHP coverage without consumer intervention is a worthy goal, but we recognize that many Exchanges do not have real-time coordination with their Medicaid/CHIP/BHP agencies in order to do so.

Comment: A few commenters expressed concerns about possible downstream effects on eligibility for future QHP coverage from putting the full responsibility for QHP termination on the Medicaid/CHIP/BHP consumer. For example, if a consumer fails to terminate QHP coverage for which APTC are paid, he may stop paying premiums because he is enrolled in Medicaid and the issuer will terminate his coverage for nonpayment. At the end of the grace period, he will still owe premium for one month of coverage after the Medicaid determination.[51] Under certain circumstances set forth in the Market Stabilization final rule,[52] the QHP issuer could then attribute payments made toward subsequent enrollments to the premium amount owed, and deny enrollment in the new coverage for failure to pay the binder payment. In regions with only one issuer, this could leave consumers who rise above the Medicaid income threshold without access to coverage options.

Response: We acknowledge there may be downstream effects on eligibility for future QHP coverage due to non-payment of premiums for those who do not terminate their coverage timely and enter a grace period. The FFEs continue to make IT improvements and enhance consumer education and outreach with the purpose of making it easier and clearer for an individual to terminate QHP coverage in a timely manner.

6. Definitions (§ 155.500)

This section defines terms that are relevant to this subpart. We proposed to amend the definitions of ''Appeal request'' and ''Appeals entity'' by adding a cross reference to proposed section § 155.716(e)'' to align with other proposals discussed throughout the proposed rule, and finalized in this rule, regarding SHOP. We did not receive substantive comments specific to this proposal, and are finalizing as proposed.

[51] This grace period only applies to APTC recipients. Termination rules for non-payment of premium default to State law for non-financial assistance enrollees, for whom the last day of coverage is generally the last day of the month in good standing.

[52] 82 FR 18349–18353.

7. Eligibility Standards for Exemptions (§ 155.605)

a. Hardship Exemptions (§ 155.605(d))

Section 1311(d)(4)(H) of the PPACA and section 5000A(e)(5) of the Code allow individuals to seek an exemption from the individual shared responsibility provision due to a lack of affordable coverage based on an individual's projected income. Although tax reform legislation enacted in December 2017 reduces to $0 the individual shared responsibility payment for months beginning after December 31, 2018, individuals may still have a need to seek a hardship exemption for 2019 and future years due to a lack of affordable coverage based on projected income. For example, individuals may continue to seek a hardship exemption after 2018 to be eligible for catastrophic coverage.

Section 155.605(d)(2) establishes the circumstances under which an Exchange must determine an applicant eligible for an exemption due to lack of affordable coverage based on projected income. For determining whether affordable coverage is available, paragraph (d)(2) states that the Exchange should use the standards specified in section 5000A(e)(1) of the Code that, among other things, specify that the Exchange should use, for individuals not eligible for employer-sponsored coverage, the annual premium for the lowest-cost bronze plan available in the individual market through the Exchange in the State in the county in which the individual resides.

However, market instability has resulted in limited offerings of plans on the Exchanges in many regions, and there may be individuals who live in a county without a bronze plan. Under the current regulation, the Exchange would not be able to make a determination as to whether an individual not eligible for employer-sponsored coverage who lives in a rating area without a bronze plan is eligible for the exemption due to lack of affordable coverage based on projected income. We proposed to amend paragraph § 155.605(d)(2)(iv), to allow an Exchange to make a determination of lack of affordable coverage based on projected income for individuals not eligible for employer-sponsored coverage using the annual premium for the lowest cost Exchange metal level plan, excluding catastrophic plans, available in the individual market through the Exchange in the State in the county in which the individual resides if there is no bronze level plan sold through the Exchange in that county. Absent this proposed change, individuals may lack access to affordable coverage, but be unable to qualify for an exemption determination from the Exchange due to the Exchange's inability to calculate whether coverage is unaffordable due to the absence of a bronze plan in that county. Under the proposed amendment to § 155.605(d)(2), Exchanges would use the amount of the lowest cost Exchange metal level plan available to the individual when no bronze level plan is available.

Comment: All commenters supported the proposed change to use the lowest cost metal level plan when calculating whether a plan is affordable in the instances when no bronze plan is available. Commenters suggested that the regulatory text clarify that the determination of the lowest-cost plan is made at the county level rather than the rating area level, and that the determination of the ''lowest-cost Exchange plan'' on which to base eligibility for an exemption should be made without consideration of catastrophic plans. Some commenters supported the proposal, but asked that the exemption not be interpreted broadly so that the exemption would weaken the risk pool. One commenter recommended that HHS bring forward the effective date of the rule to plan year 2018.

Response: We are finalizing this policy, and are clarifying that eligibility for an exemption should be made at the county level and without consideration of catastrophic plans. We appreciate the concerns about the risk pool, but believe that this change is targeted specifically to handle the issue of when no bronze plans are available to the individual. This change will be effective on the effective date of this rule, which occurs during the 2018 plan year.

b. Required Contribution Percentage (§ 155.605(e)(3))

Under section 5000A of the Code, an individual must have minimum essential coverage for each month, qualify for an exemption, or make an individual shared responsibility payment. 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. Although tax reform legislation enacted in December 2017 reduces to $0 the individual shared responsibility payment for months beginning after December 31, 2018, individuals may continue to seek a hardship exemption based on the required contribution amount after 2018 to obtain catastrophic coverage. Further, 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. As such, we are continuing to finalize the excess of the rate of premium growth over the rate of income growth and the required contribution percentage for the 2019 benefit year below.

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 of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period.

We established a methodology for determining the excess of the rate of premium growth over the rate of income growth for plan years after 2014 in the 2015 Market Standards Rule (79 FR 30302), and we stated that 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.[53]

[53] 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,

Continued

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.[54] (As discussed elsewhere in this preamble, we are finalizing the proposed 2019 premium adjustment percentage of 1.2516634051, (or an increase of about 25 percent over the period from 2013 to 2018). This reflects an increase of about 7.7 percent over the 2018 premium adjustment percentage (1.2516634051/1.1617303196).)

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 2019 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year ($53,729 for 2018) exceeds per capita PI for 2013 ($44,555), carried out to ten significant digits. The ratio of per capita PI for 2018 over the per capita PI for 2013 is estimated to be 1.2059028167 (that is, per capita income growth of about 20.6 percent). This reflects an increase of about 4.5 percent relative to the increase for 2013 to 2017 (1.2059028167/1.1540603665) used in the 2019 Payment Notice final rule.

Thus, using the 2019 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2018 is 1.2516634051/1.2059028167, or 1.0379471610. This results in a required contribution percentage for 2019 of 8.00 * 1.0379471610 or 8.30 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.25 percentage point from 2018 (8.30358–8.05317).

We sought comment on whether there are other measures of premium growth or income growth that we could use to calculate the required contribution percentage.

Comment: We received no comments on other measures of premium growth or income growth that we could use to calculate the required contribution percentage. One commenter supported the current methodology, saying it provides consistency and stability, given highly volatile premiums.

Response: We are finalizing the required contribution percentage as proposed.

8. Eligibility Process for Exemptions

Section 155.610(h)(2) describes the timeframe during which the Exchange will accept an individual's application for a hardship exemption. We proposed to make a technical correction to § 155.610(h)(2) to reflect the prior redesignation of paragraph § 155.605(g)(1), which describes the criteria for a hardship exemption, to § 155.605(d)(1) in the 2017 Payment Notice.[55]

Commenters did not oppose this correction, and we are finalizing as proposed.

9. Exchange Functions: Small Business Health Options Program

We previously interpreted the PPACA's provisions regarding the SHOPs to require that all SHOPs provide for employer eligibility, employee eligibility, and certain enrollment functions, including premium aggregation functions.

As we have stated in previously released guidance,[56] the FF–SHOPs and the SBE–FPs for SHOPs have seen lower than expected enrollment, to date. As of January 1, 2017, approximately 7,554 employer groups were enrolled in the FF–SHOPs, covering 38,749 lives. Further, we recognize that many SHOPs, including FF–SHOPs, continue to face challenges and, to accommodate those challenges and to provide SHOPs with more flexibility in operating their programs, we proposed to allow SHOPs to operate in a leaner fashion beginning for plan years beginning on or after January 1, 2018. We are generally finalizing the policies as proposed, and describe changes to certain of the regulations later in this section of the preamble. These changes will be effective as of the effective date of this rule. In the 2018 Payment Notice, HHS finalized the removal of a participation provision that had required certain QHP issuers to participate in an FF–SHOP in order to participate in an FFE. As a result, HHS expected a significant decrease in the number of issuers in the FF–SHOPs in the 2018 plan year and fewer enrollments in the FF–SHOPs and SBE–FPs for SHOP. With the significant decreases in SHOP QHP issuer participation and enrollment for plan year 2018, and, due to lower than expected enrollment in the FF–SHOPs and SBE–FPs for SHOP to date, it is not cost effective for the Federal government to continue to maintain certain FF–SHOP functionalities, collect significantly reduced user fees on a monthly basis, maintain the technologies required to maintain an FF–SHOP website and payment platform, generate enrollment and payment transaction files, and perform enrollment reconciliation.

We proposed to remove regulatory burden on SHOPs by removing several of the existing requirements imposed upon the SHOPs, focusing on removing requirements to provide certain functionality that is not expressly required by the PPACA, while still ensuring appropriate implementation of statutorily required functions of the SHOP. Under the proposals, employer groups that are currently enrolled in a SHOP QHP for plan years that began prior to January 1, 2018, would not be affected by the proposed changes to enrollment through a SHOP. We are generally finalizing this rule as proposed, and describe changes to certain of the regulations later in this section of the preamble. The changes will take effect for plan years beginning on or after January 1, 2018, as of the effective date of this rule.

Under the approach we proposed and are finalizing, SHOPs will no longer be required to provide employee eligibility, premium aggregation, and online enrollment functionality for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. The FF–SHOPs, and SBE–FP for SHOPs, will take advantage of these flexibilities. Despite the removal of several regulations on SHOPs, State Exchanges will continue to have the flexibility to operate their SHOPs as they choose, in accordance with applicable Federal and State law. Notably, we received comments to the Request for Information that provided support for this proposed enrollment approach. Moreover, a few State Exchanges currently utilize a similar enrollment approach as is being finalized as a transitional measure that was expected to extend through plan years beginning in 2018. These SBEs have already inquired about continuing to permit enrollment of their SHOP

rounded to the nearest one-hundredth of one percent.

[54] 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 preceding year exceeds the most recent NHEA estimate of per enrollee employer-sponsored insurance premiums for 2013.

[55] 81 FR 12346 (March 8, 2016).

[56] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/The-Future-of-the-SHOP-CMS-Intends-to-Allow-Small-Businesses-in-SHOPs-Using-HealthCaregov-More-Flexibility-when-Enrolling-in-Healthcare-Coverage.pdf.*

consumers through a participating QHP SHOP issuer, or a SHOP-registered agent or broker, for plan years beginning in 2019 and beyond.[57] Additionally, these SBEs have each indicated that this enrollment method has contributed to reduced SHOP Exchange programmatic expenses, which is critical for SBEs to maintain financial sustainability as required by section 1311(d)(5)(A) of the PPACA.

We are finalizing the modifications throughout the requirements applicable in the SHOPs for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. However, because some groups' plan years that begin prior to the effective date of this final rule will continue beyond the effective date of this rule, both the existing requirements applicable to plans beginning before January 1, 2018, and the new requirements applicable to plans beginning after January 1, 2018 will need to be in place simultaneously. For this reason, we are finalizing our proposal to make many of the existing regulatory sections regarding SHOP applicable for plan years beginning prior to January 1, 2018 only, and new regulatory sections applicable for plan years beginning on or after January 1, 2018. After the effective date of this rule, the new regulatory sections will be effective for all 2018 plans, regardless of whether the plans started prior to the effective date of the rule. Except as described in this rule, we proposed and now finalize that these new regulatory sections will mirror the existing regulatory sections.

Specifically, we proposed to amend §§ 155.705, 155.715, 155.720, 155.725, 155.730, 155.735, 155.740, 156.285 and 157.205 to make each section applicable only to plan years beginning prior to January 1, 2018. Additionally, we proposed to introduce mirroring new sections, applicable for plan years beginning on or after January 1, 2018, at §§ 155.706, 155.716, 155.721, 155.726, 155.731, 155.741, 156.286 and 157.206. We did not propose a new section mirroring current § 155.735, as further explained later in this preamble. We also proposed minor changes to § 155.700. These are described in the sections that follow. We also proposed additional changes related to the proposed new approach to SHOP in §§ 155.106, 155.200, and 156.350, to define the streamlined enrollment approach that groups enrolling in a SHOP QHP in an SBE–FP for SHOP will take when this rule becomes effective. In light of the substantial changes, we have made conforming amendments and updated applicable cross references in these and other regulations, including §§ 147.102, 147.104, 155.500, 156.200, and 156.340.

We are finalizing the following policies as proposed. SHOPs that opt to operate in a leaner fashion, such as the FF–SHOPs, will still assist qualified employers who are small employers in facilitating the enrollment of their employees in QHPs offered in the small group market in the State, consistent with section 1311(b)(1)(B) of the PPACA, because the basic functionalities of an Exchange will still be provided. SHOPs will continue to be required to certify plans for sale through a SHOP, and the following features will still be available: An internet website that displays and provides QHP information, a premium calculator that generates estimated prices of the available QHPs, and a call center to answer questions related to the SHOP. Further, small employers will continue to obtain an eligibility determination from the SHOP website but will enroll in a SHOP QHP by working with a SHOP-registered agent or broker, or with a QHP issuer participating in a SHOP to complete the enrollment process.

An enrollment completed by working with a SHOP-registered agent or broker, or with a QHP issuer participating in a SHOP in the SHOPs that decide to operate in a leaner fashion, like the FF–SHOPs, will be considered to be an enrollment through a SHOP, and an employer will be considered to have offered its employees coverage through a SHOP for purposes of section 45R of the Code (the Small Business Health Care Tax Credit), if the employer: (1) Obtains from the SHOP a favorable determination of eligibility to participate in the SHOP; (2) enrolls in a SHOP QHP offered by an issuer; and (3) chooses to have the enrollment identified as being through the SHOP. If an enrollment meets this definition, the QHP issuer will be required to conduct enrollment with all applicable SHOP rules and policies.

Because SHOPs will be required to determine employer eligibility to participate in a SHOP only, and will not be required to determine employer group members' eligibility to enroll, SHOPs will only be required to handle appeals as they relate to an employer's eligibility in a SHOP, as currently described in § 155.740. If, under the flexibilities described here, employer group members enrolled in a SHOP QHP needed to file an appeal related to their SHOP coverage, they generally will file the appeal directly with the insurance company, or could take advantage of other appeals mechanisms under applicable State and Federal law. If an employer group member enrolled in coverage though a SHOP operating under the flexibilities outlined in this rule and believes that he or she were entitled to a SHOP special enrollment period, but was denied that special enrollment period, the employer group member could file a complaint with the SHOP and the SHOP will investigate. SHOP special enrollment periods will continue to be available to enrollees who experience specified qualifying events. SHOPs that use the new flexibilities, such as the FF–SHOPs, will no longer have the information required to determine employer group members' eligibility for special enrollment periods. Therefore, issuers wishing to participate in such a SHOP will be required to administer special enrollment periods.

SHOPs opting to operate in a leaner fashion, like the FF–SHOPs, will continue to provide employers with the option to offer a choice of plans, consistent with section 1312(a)(2) of the PPACA, by continuing to allow employers to offer their employees a choice of plans, either by coverage level, or, in some States, by participating QHP issuer. Employers will be able to see the SHOP plans available, by coverage level and issuers, in their area using the plan comparison tool available on a SHOP website. Employers who choose to offer a choice of plans to employees would contact the participating QHP issuers whose plans they would like to offer to their employees to obtain the application information necessary in order to enroll in coverage.

Once the necessary information required to enroll is obtained from the QHP issuer or issuers or from the SHOP-registered agent or broker, the employer could disseminate the application information to its employees. The employer could later collect the information from its employees and send it to the applicable QHP issuer or issuers or the SHOP-registered agent or broker. Employers generally will also be responsible for collecting monthly premium payments from employees and sending them to the appropriate issuers. While initially offered to support employers' option to offer a choice of plans across issuers, premium aggregation functions are not a function mandated by the PPACA and therefore may be altered or removed, as previously proposed and now finalized with this rule. SHOP-registered agents and brokers will be able to assist employers in performing these tasks, if

[57] Extension of State-based SHOP Direct Enrollment Transition (April 18, 2016), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/1332-and-SHOP-Guidance-508-FINAL.pdf.*

the employer chooses to work with a SHOP-registered agent or broker.

Additionally, to further support employers' option to offer a choice of plans across issuers, under the proposals we are finalizing, an employer's minimum participation rate will continue to be calculated at the employer level, though the SHOPs will not be required to calculate it, and the FF–SHOPs will no longer calculate it. No changes were proposed to the way in which an employer's minimum participation rate is calculated or to the 70 percent minimum participation rate default in FF–SHOPs. Participating QHP issuers will not be permitted to deny enrollment on the basis of failure to meet minimum participation requirements to employers who have been determined eligible to participate in the SHOP, and who have met the applicable minimum participation rate, as specified by the SHOP, even if only one employee in a group wishes to enroll with a particular issuer.

Under the approach we proposed and are finalizing, SHOPs will also still be able to administer the provision at section 1304(b)(4)(D) of the PPACA that guarantees continuing eligibility for growing small employers by limiting the validity of an employer's eligibility determination such that it terminates when the employer makes a change that could end its eligibility under § 155.710(b), by requiring the employer to submit a new single employer application to the SHOP if the employer makes a change that could end its eligibility under § 155.710, and by requiring issuers to be able to distinguish SHOP enrollments from non-SHOP enrollments. Under the flexibilities being finalized, issuers will be expected to rely on the determination of eligibility to reflect the employer's ongoing eligibility to participate in the SHOP, and the IRS will have the option to follow up with an employer for additional information if necessary.

HHS understands that the changes outlined in this final rule will allow SHOPs to adopt changes (and that the FF–SHOPs will adopt such changes) that result in a substantial departure from current operations for participating SHOP QHP issuers, employers, and enrollees. It is important to note that employer groups enrolled in a SHOP plan that began in 2017 in a SHOP that will opt to operate in a leaner fashion, like the FF–SHOPs, will not be affected until their plan year ends, as the current regulations will be in effect for the entirety of a plan that began in 2017. We recognize that some employers have already completed an enrollment that took effect on or after January 1, 2018. The current regulations will also be in place for the beginning of plan year 2018 for those plans that start before the effective date of this rule. But, after the effective date of this rule, the finalized regulations pertaining to plan year 2018 will be effective for all plans that begin or began in 2018, regardless of whether the enrollment occurred prior to the effective date. HHS acknowledged that this transition would create challenges and was concerned about employers enrolling between when rates become available for plan years beginning in 2018 and when the flexibilities in this rule will go into effect. We sought comment on how to best ease this transition and did not receive any comments on this point. In addition, we released guidance on this issue in conjunction with the release of the proposed rule.[58]

Because many comments focused on the general approach we had proposed for SHOPs, we have summarized comments related to SHOP proposals here, with a few exceptions, rather than after summarizing the proposed amendments to each section.

Comment: Many commenters supported our proposal to remove many of the regulatory requirements imposed upon SHOPs. Some commenters expressed concern over our proposal to remove the regulatory burden on SHOPs, stating that removing such requirements does not address the reasons the SHOP Exchanges have been unattractive to small employers. We received a comment specifically noting that SHOPs saw low enrollment for reasons other than a poor enrollment system. Some commenters requested that HHS should require that State Exchanges either operate entirely under the SHOP regulations prior to them being amended or otherwise identically to how the FF–SHOP will operate. We also received a comment stating that removing many of the requirements on SHOPs will also do away with a centralized system for free and impartial information for small employers looking for coverage. One commenter noted that the proposals would impose an additional burden on agents, brokers, and issuers without providing additional compensation.

Response: We are finalizing the policies as proposed, with minor, mostly non-substantive adjustments further described in the following sections of the preamble. The primary purpose of these regulatory changes was not to increase the attractiveness of SHOPs to small employers, but to remove the regulatory burden on SHOPs to give Exchanges the flexibility to operate their SHOPs in a cost-effective way that best meets the needs of their State's small group market. We believe this rule achieves that primary purpose. Nonetheless, under this rule, SHOPs will continue to offer a centralized system that will provide certain free and impartial information to small employers looking for coverage. For example, all SHOPs, including FF–SHOPs, will still be required to make a premium calculator available. This calculator will provide small employers seeking SHOP coverage with free and impartial information about the SHOP QHP and stand-alone dental plan QHP options available in their area. With regard to any burden on agents, brokers, and issuers, we believe that the proposed changes will reduce, rather than increase, the burden for agents, brokers and issuers. For example, in SHOPs that use the finalized flexibilities, issuers will no longer be required to maintain the infrastructure to connect with SHOPs, and agents and brokers who assist small groups in enrolling in SHOP coverage will use the issuer enrollment channels they are most familiar with, not a SHOP website. As previously noted, given the reduction in issuer participation in the SHOPs, HHS believes the impact of removing the requirement to maintain premium aggregation functions, which the FF–SHOPs and SBE–FPs for SHOP will no longer have, will be minimal. HHS also notes that State Exchanges are encouraged to continue to operate their SHOPs as they do today, or design a SHOP within the bounds of the flexibilities being finalized within this final rule.

Comment: We received comments seeking clarification on the applicability of other Exchange requirements to SHOPs where we did not explicitly propose changes. Specifically, we received comments requesting clarification on whether HHS will collect SHOP enrollment data under § 155.1200(b)(2) from either States or issuers, in States where the Exchange pursues the flexibilities outlined herein, such as the FF–SHOP States. We also received a comment seeking clarification on whether States that operate under the flexibilities described herein would be required to perform enrollee satisfaction surveys, as described under § 155.200(d).

Response: HHS recognizes that Exchanges that operate under these

[58] CMS to Allow Small Businesses and Issuers New Flexibilities in the Small Business Health Options Program (SHOP) For Plan Year 2018 (October 27, 2017), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/New-Flexibilities-SHOP-2018.pdf.*

SHOP flexibilities may not have records of SHOP enrollments, and as such, does not expect these Exchanges to submit SHOP enrollment data to HHS under § 155.1200(b)(2). QHP issuers are required to contract with an HHS-approved enrollee satisfaction survey vendor to administer the enrollee satisfaction survey of QHPs' enrollees, and Exchanges, including SHOPs, are merely required to continue overseeing implementation of the enrollee satisfaction surveys, as described at § 155.200(d).

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

Section 155.700 outlines the general requirements to establish a SHOP and defines certain terms specific to SHOPs. We proposed to amend § 155.700(a) by adding paragraph (a)(1) to make the current requirements applicable for only plan years beginning prior to January 1, 2018. We proposed to add paragraph (a)(2) to describe the general requirements applicable for plan years beginning on or after January 1, 2018. Proposed paragraph (a)(2) more closely aligns with the statutory language in section 1311(b)(1)(B) of the PPACA than existing paragraph (a), and will specify that SHOPs must assist qualified employers in facilitating the enrollment of their employees in small group market QHPs. We believe that the PPACA does not have to be interpreted to require SHOPs to process the enrollment of qualified employees into QHPs, as is required by the current regulation. Instead, we believe it can also be interpreted in a less burdensome way, to require SHOPs to assist qualified employers in facilitating employees' enrollment into QHPs, which will still be provided for under our proposals. We sought comment on this proposal.

We are finalizing as proposed; these changes will be effective as of the effective date of this rule. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

b. Functions of a SHOP (§ 155.705) for Plan Years Beginning Prior to January 1, 2018 (§ 155.705)

As discussed in the following section, we proposed to modify the regulatory requirements regarding functions of a SHOP for plan years beginning on or after January 1, 2018, and to introduce those requirements in a new § 155.706. To reflect the proposal that the requirements currently in § 155.705 will apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.705 and add paragraph (f), to state that the section would apply only for plan years that begin prior to January 1, 2018. We discuss new § 155.706 below.

We are finalizing this policy as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

c. Functions of a SHOP for Plan Years Beginning on or After January 1, 2018 (§ 155.706)

Section 155.705 describes required Exchange functions that are specific to SHOPs. To permit SHOPs to operate in a leaner fashion for plan years beginning on or after January 1, 2018, we proposed several changes to the required functions of a SHOP to become effective as of the effective date of this rule. Under these proposals, which we proposed to introduce in new § 155.706, certain functions that are currently required would become optional for SHOPs for plan years beginning on or after January 1, 2018, and the FF–SHOPs would not provide them. With the exception of the proposed changes to the functions described here, the functions would remain the same as in § 155.705. We proposed only to include the paragraphs in current paragraph (b)(3) of § 155.705, that would be applicable to plan years beginning on or after January 1, 2018, maintaining the currently applicable policy requiring SHOPs to allow employers to select a level of coverage and to offer a choice of QHPs across that level of coverage, and permitting SHOPs to allow employers to offer a choice of all QHPs from a single issuer, or another method of providing employer choice. To provide additional flexibility, we also proposed to codify that State Exchanges may, as the FF–SHOPs have, offer employers a choice of SADPs in their SHOPs. To reflect the proposals described in § 156.150(b) of this document, we proposed that State Exchanges could, and FF–SHOPs would, allow employers to offer a choice of SADPs in their SHOP. If no SADP coverage levels are available, employers would be able to offer a choice of all SADPs offered in an area. We also proposed conforming amendments to the structure of this paragraph.

Because, as discussed earlier in this preamble, premium aggregation functions are not mandated by the PPACA and to maximize the flexibilities associated with operating a SHOP, we proposed to remove required functions related to premium aggregation. Specifically, we proposed that the only premium aggregation function from § 155.705(b)(4) that would be applicable in plan years beginning on or after January 1, 2018, would be an amended version of the function in § 155.705(b)(4)(ii)(A), relating to the continuation of coverage. State Exchanges would be permitted to continue providing remaining premium aggregation functions in their SHOPs currently described at § 155.705(b)(4) if they choose to do so. SHOPs electing not to provide premium aggregation functions, like the FF–SHOPs, would still be required to provide an opportunity for employers to offer employees a choice of plans. In SHOPs not offering premium aggregation functions, we stated that we expected that employers generally would receive premium bills from each of the plans or issuers with which an employee enrolls and will pay premiums to each such plan or issuer. Section 155.705(b)(4)(ii)(A) (which we proposed to include in a revised form in § 155.706) describes the process through which the SHOP may enter into an agreement with a qualified employer related to the administration of continuation coverage. Under the approach for enrollment in a SHOP QHP for plan years beginning on or after January 1, 2018, the FF–SHOPs would no longer facilitate the collection of premiums. Therefore, we proposed that § 155.706(b)(4) would mirror § 155.705(b)(4)(ii)(A), but would not include the provision that permits the FF–SHOPs to limit the service to the collection of premiums related to the requirements under 29 U.S.C. 1161, *et seq.*

Paragraph (b)(7) of § 155.705 describes the SHOP function related to QHP availability in merged markets and paragraph (b)(8) describes the function related to QHP availability in unmerged markets. We proposed to include these functions in § 155.706(b)(7) and (b)(8).

However, under the proposal to streamline SHOP enrollment for plan years beginning on or after January 1, 2018, we proposed to change the references to a ''qualified employee'' to an ''employer group'' in both paragraphs, as the SHOP would no longer be required to process employee enrollments.

Paragraph (b)(10) of § 155.705 establishes requirements related to minimum participation rates and SHOP coverage; we proposed to include these requirements in § 155.706(b)(10), with certain modifications. In order to facilitate employers' ability to offer employees a choice of plans through a SHOP, as is required under section 1312(a)(2) of the PPACA, § 155.705(b)(10) requires that any

minimum participation rate applicable in a SHOP be calculated based on the rate of employee participation in the SHOP, rather than on the rate of participation in any particular QHP or QHPs of any particular issuer. In the FF–SHOPs, this requirement has been implemented through the requirements currently outlined at § 155.705(b)(10)(i)–(iii). Currently, the FF–SHOPs calculate a group's minimum participation rate based on the information provided by the employer and the employees during online enrollment. Under the approach we proposed, SHOPs would not be required to collect the enrollment information needed to calculate a group's minimum participation rate. Issuers would be permitted to use their established practices allowed under State law for groups enrolling in their certified SHOP plans for plan years beginning on or after January 1, 2018, so long as they comply with § 147.104, and so long as the minimum participation rate is calculated based on the level of participation in the SHOP instead of on the level of participation in any one QHP or with any one issuer (that is, so long as SHOP participation is measured at the employer group level). We did not propose to make any changes to the way in which the minimum participation rate in SHOPs is calculated or the default 70 percent minimum participation rate used in the FF–SHOPs unless otherwise determined by a State. Issuers participating in the FF–SHOPs would be required to adhere to the level of participation as would continue to be specified in § 155.706(b)(10), and issuers offering QHPs in State Exchanges would be subject to any minimum participation rate established by the SHOP, consistent with this provision. We also proposed that § 155.706(b)(10) would not include the language in § 155.705(b)(10)(i) because it applies to plan years beginning before January 1, 2016, and would therefore not be applicable for the period covered in § 155.706. We also proposed to clarify that, under the proposed approach, the reference in proposed § 155.706(b)(10) to the time the employer submits the SHOP group enrollment would be interpreted to mean the time when the employer submits a complete group enrollment or renewal to the QHP issuer or SHOP-registered agent or broker, if applicable.

Section 155.705(b)(11) specifies the requirements related to an online premium calculator. For plan years beginning on or after January 1, 2018, we proposed to modify these requirements and include the modified requirements in § 155.706(b)(11). Specifically, § 155.706 (b)(11) would specify that the premium calculator described in § 155.205(b)(6) must facilitate the comparison of available QHPs. This would reflect that SHOPs would no longer be required to maintain enrollment and premium payment information or administer premium billing, and therefore, would no longer necessarily have employer contribution information. SHOPs would be required to maintain a calculator that facilitates the comparison of available QHPs and would generate premium estimates, but would no longer be required to reflect any employer contribution. Therefore, we proposed to not include the requirements in § 155.705(b)(11)(i) or (ii) in § 155.706(b)(11), since these reflect methods SHOPs would use for determining employer contributions. In the FF–SHOPs, this premium calculator would be where an employer or SHOP-registered agent or broker could go to see a complete listing of all the QHPs available in a given area. The tool has served and would continue to serve as a resource for employers and SHOP-registered agents and brokers. Because we believe the premium calculator requirement at section 1311(d)(4)(G) of the PPACA could be interpreted to apply to only individual market Exchanges based on its reference to APTCs and CSRs, which are not available through SHOPs, we believe that this proposal is consistent with the statute.

Section 155.705(c) generally requires a SHOP to provide data related to eligibility and enrollment of a qualified employee to the applicable individual market Exchange. For plan years beginning on or after January 1, 2018, we proposed that this requirement would apply only in SHOPs that collect employee enrollment data related to eligibility and enrollment of a qualified employee, unless the SHOP is operated pursuant to § 155.100(a)(2).

Finally, we proposed in paragraph (e) that the provisions of the section would be applicable for plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed, except that we are finalizing minor changes to reflect the changes to the actuarial value requirements for SADP QHPs in § 156.150 of this rule, and small, nonsubstantive changes to the regulatory text for clarity and consistency; these policies will be effective as of the effective date of this rule.

Comment: We received a few comments regarding the minimum participation rate in SHOPs. One commenter requested that we maintain the 70 percent minimum participation rate in FF–SHOPs, and another requested that the 70 percent minimum participation rate be lowered. We also received a comment disagreeing with the intent of the proposals within this section. A commenter noted that groups that do not meet the minimum participation rate should not be permitted to enroll in coverage. Finally, a commenter requested that HHS continue to promote the annual 1-month window in which the minimum participation rate does not apply.

Response: In our proposed changes to SHOPs, we did not propose to change the applicable minimum participation rate, or the way in which the minimum participation rate is calculated. The FF–SHOPs will continue to maintain a minimum participation rate of 70 percent unless otherwise specified by the State. This percentage is consistent with industry standards. The annual 1-month window from November 15–December 15, when employers can enroll in a SHOP QHP without meeting any minimum participation rate for their State, will remain in place. This window aligns with the guaranteed availability standards outlined in the PPACA.

Comment: We received a comment in support of our proposal to codify an employer's ability to offer a choice of SADPs and our proposal to allow employers to offer a choice of all SADPs offered through a SHOP, in accordance with the proposals made elsewhere in this rule to remove actuarial values for SADPs.

Response: We are finalizing this policy as proposed, with revisions to the regulation text to reflect the changes to the actuarial value requirements for SADP QHPs, as noted in the proposed rule, and to clarify that the third option refers to all SADPs offered in an area by a single issuer. We also added a title for paragraph (b)(4) that was inadvertently omitted in the proposed rule.

Comment: We received a comment requesting that the option for States to submit an annual letter opting out of the third method of employee choice, a choice of all plans offered by a single issuer, be removed.

Response: We did not propose to remove this option in the proposed rule, and are finalizing this section as described earlier in the preamble for this section. We continue to believe it is important for States to have a choice regarding whether employee choice of all QHPs offered by a single issuer applies in their markets.

Comment: One commenter noted that without premium aggregation, it is difficult or impossible for small businesses to offer a choice of multiple

insurers and plans to their employees. The commenter recommended that HHS provide data on the number of employers currently offering employee choice in the FF–SHOPs and provide annual updates on that data, so that HHS, stakeholders, and policymakers can monitor the impact of this change on employee choice in SHOP.

Response: As discussed throughout this preamble, HHS believes that the PPACA does not have to be interpreted to require SHOPs to provide premium aggregation functions and thus is finalizing the proposals to allow SHOPs to not provide premium aggregation functions other than those related to continuation of coverage under finalized § 155.706(b)(4). State SHOPs are permitted to continue offering premium aggregation functionality. While we recognize that the elimination of premium aggregation in the FF–SHOPs could increase the administrative burden on employers, we believe that potential increased burden is outweighed by the other benefits to the SHOPs and, ultimately, to the employers described throughout this preamble regarding the changes to the SHOPs. Under the proposals being finalized in this rule, SHOPs will not be required to have access to ongoing enrollment information, and the FF–SHOPs will not require issuers to report SHOP employee choice enrollment information to HHS.

d. Eligibility Determination Process for SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.715)

As discussed in the following section, we proposed to modify the regulatory requirements regarding the eligibility determination process for SHOP for plan years beginning on or after January 1, 2018, effective on the effective date of this rule, and to introduce those requirements in a new § 155.716. To reflect that the requirements currently in § 155.715 will apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.715 and add paragraph (h), to state that the section applies only for plan years that begin prior to January 1, 2018.

We are finalizing this section as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

e. Eligibility Determination Process for SHOP for Plan Years Beginning on or After January 1, 2018 (§ 155.716)

Section 155.715 describes the SHOP eligibility determination process for employers and employees. We proposed to add new § 155.716 to describe the eligibility determination process for SHOPs for plan years beginning on or after January 1, 2018. With the exception of the changes to the process described here, the process will remain the same as in § 155.715. However, this new section will modify and remove some of the requirements in § 155.715. The proposals described in this section will be effective on the effective date of this rule.

Section 155.715(a) requires that before permitting the purchase of coverage in a QHP, a SHOP must determine that the employer or individual who requests coverage is eligible. This requirement means that employers and employees must complete an application to participate in a SHOP. Accordingly, the FF–SHOPs have established certain operational requirements related to submitting an application through the FF–SHOP website, including providing information on the business (including location, Employer Identification Number, and number of employees), and identity verification.

To reduce the barriers on employers to obtain SHOP coverage, we proposed in § 155.716 that SHOPs must determine that the employer who requests coverage is eligible, but that SHOPs generally would not always need to do so before the issuer permits the purchase of coverage in a QHP through a SHOP, for plan years beginning on or after January 1, 2018. This would generally permit an employer to purchase a QHP before obtaining a determination of SHOP eligibility and confirming with the issuer the status of the enrollment as being through the SHOP. As further explained in the preamble to § 156.286, issuers would be expected to establish processes to ensure that they can accurately identify which enrollments are considered SHOP enrollments and which are not. We encouraged employers to obtain an eligibility determination from a SHOP as close to the date in which they purchase a SHOP QHP as possible. We considered establishing a limit on how long an employer can wait between purchasing the QHP and obtaining the determination of eligibility for that QHP to be considered purchased through the SHOP. We solicited comments on whether to establish such a limit, and how long it should be. Ultimately, we are finalizing this policy as proposed, and are not establishing a timeline under which employers must obtain an eligibility determination from a SHOP for their enrollments to be considered through the SHOP.

As a condition of claiming the Small Business Health Care Tax Credit, small employers must be prepared to provide sufficient proof that they meet applicable criteria. Part of the employer's responsibility in providing evidence that it is a small employer eligible for the Small Business Health Care Tax Credit includes the ability to verify not only the purchase of a SHOP QHP, but the ability to produce a favorable eligibility determination from a SHOP. Therefore, employers applying for the Small Business Health Care Tax Credit are also encouraged to obtain an eligibility determination from the SHOP in the taxable year in which they intend to apply for the credit.

Section 155.715(b) requires the SHOP to accept SHOP applications from both employers and employees, and § 155.715(c) provides for the verification of both employer and employee eligibility. For plan years beginning on or after January 1, 2018, we proposed to provide SHOPs flexibility to forgo providing for employee eligibility determinations and related functionality and obligations (and the FF–SHOPs will pursue this flexibility). We proposed that SHOPs would not be required to accept applications by employees or determine eligibility of employees because, under the proposed approach to enrollment in a SHOP, SHOPs will not be required to interact with employees. Proposed paragraphs (b) and (c) of § 155.716 would still require SHOPs to accept a SHOP single employer application form from employers, and to verify employer eligibility subject to provisions like those currently in § 155.715(c)(2) through (4). We have updated and made available a single employer application that SHOPs can use to determine employer eligibility to participate in the SHOP to reflect the new rule at § 155.731, described elsewhere in this preamble. Currently, employee information is primarily collected for purposes of enrollment, and therefore will not be necessary for SHOPs to collect under the approach we are finalizing, allowing SHOPs to operate in a leaner fashion. State Exchanges that intend to maintain more robust SHOP functionalities, in lieu of the flexibilities adopted in this rule, will be permitted to continue to determine employee eligibility. We believe this proposal is consistent with the statute because, as noted above, the PPACA does not have to be interpreted to require SHOPs to provide for employee enrollment functionality, and does not define qualified employees.

Paragraph (d) of § 155.715 describes the eligibility adjustment period. We proposed to include in § 155.716(d) these requirements as they relate to eligibility for employers. However,

because SHOPs will not be required to accept applications from employees, we proposed not to include the requirements in § 155.715(d)(2), relating to eligibility for employees, in new § 155.716. We also proposed to add language to reflect that SHOPs also must address inconsistencies in employer eligibility information received from sources other than those used in the employer eligibility process described in § 155.715(c).

To reflect our proposed changes to the employer eligibility verification process, as further described in this section and in the preamble to § 157.205, and our proposal not to include a section mirroring § 155.735 regarding terminations, we are adding a requirement in the paragraphs mirroring paragraphs (d)(3)(i) and (e) of § 155.715 to require the SHOP to notify employers not only of a denial of the employer's eligibility to participate in the SHOP, but also of a termination of the employer's eligibility to participate in the SHOP.

Paragraph (f) of § 155.715 specifies the requirement that the SHOP notify an employee of his or her eligibility to enroll in a SHOP. Because we will not be requiring SHOPs to determine employee eligibility for plan years beginning on or after January 1, 2018, we proposed not to include this requirement in § 155.716. SHOPs that continue to provide employee eligibility functionality should continue notifying employees of their eligibility. In the SHOPs that operate in a leaner fashion, like the FF–SHOPs, we anticipate that the participating QHP issuer or employer will determine the method of employee enrollment and notification, consistent with otherwise applicable Federal or State law.

Paragraph (g) of § 155.715 describes the requirements surrounding communication between the SHOP and QHP issuers in the event of an employer withdrawing from the SHOP and the notification of qualified employees of an employer's withdrawal from SHOP. Under the proposed approach for SHOPs beginning for plan years that begin on or after January 1, 2018, the enrollment and disenrollment processes would be addressed between the employer and the issuer or the agent or broker. Therefore, we proposed not including these requirements in § 155.716.

We further proposed in paragraph (f) of § 155.716 that an employer's determination of eligibility to participate in the SHOP obtained under paragraph (a) remains valid until the employer makes a change that could end its eligibility under § 155.710(b). This could include terminating offers of coverage to employees maintaining full-time status, growing to be a large employer without having maintained continuous SHOP coverage, or moving its principal business address or eligible employee worksites out of the SHOP service area. The employer will be required under new regulations being finalized in part 157 to take further action upon termination of the validity of the determination of eligibility to participate in a SHOP to submit a new application for determination of eligibility or to withdraw from participation in the SHOP. We considered requiring SHOPs to acknowledge an employer's withdrawal from participation in the SHOP within a reasonable time. Alternatively, we considered requiring that employers reapply to determine their SHOP eligibility on an annual basis. We sought comment on these proposals, and ultimately are moving to finalize our proposal without requiring employers to reapply to determine their SHOP eligibility on an annual basis or requiring SHOPs to acknowledge such a withdrawal.

We proposed to specify in paragraph (g) that the provisions in § 155.716 will be applicable for plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed. These changes will become effective as of the effective date of this rule.

Comment: We received several comments urging us not to establish a 30-day timeline on employers to obtain an eligibility determination because the timeframe would be burdensome on employers. We received comments from State Exchanges also recommending that no timeline should be established for SHOP. These State Exchanges do not impose such a timeline in their SHOPs and have found success with the model.

Response: We are finalizing this section as proposed, and no timeline will be imposed on employers to obtain an eligibility determination from a SHOP. We note that issuers may require employers to obtain an eligibility determination from the SHOP as a condition of enrollment when there is a legal basis for restricting enrollment to enrollment through the SHOP. Further, the IRS may request to see an employer's eligibility determination from the SHOP if the employer chooses to apply for the Small Business Health Care Tax Credit.

Comment: We received one comment regarding whether employers should be required to notify a SHOP of their intent to withdraw from a SHOP, and if a SHOP should acknowledge an employer's withdrawal. The commenter recommended that we not require employers to notify the SHOP of their intent to withdraw their participation from a SHOP and, therefore not require SHOPs to acknowledge an employer's withdrawal.

Response: Although we appreciate the commenter's suggestion as another way to ease burden on employers, for SHOPs to be able to determine which employers remain eligible to participate, the rules must impose some obligation on employers to notify the SHOP when their eligibility ends. As such, as further described in the preamble to § 157.206, we are finalizing our proposal that requires employers to submit a new single employer application to the SHOP or withdraw from participating in the SHOP if the employer makes a change that could end its eligibility under § 155.710 of this subchapter. As noted above, SHOPs will not be required to acknowledge an employer's withdrawal.

f. Enrollment of Employees Into QHPs Under SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.720)

Section 155.720 contains requirements related to the enrollment of employees into QHPs under SHOP. To reflect that our proposed approach would no longer require SHOPs to provide functionality related to enrollment of employees for plan years beginning on or after January 1, 2018, we proposed to amend the heading of § 155.720 and add paragraph (j), to state that the section will apply only for plan years that begin prior to January 1, 2018.

Specifically, we proposed that the requirement in paragraph (b) of § 155.720 that SHOPs establish a timeline and process for QHP issuers and employers to follow regarding purchasing coverage and processing of enrollment would not be applicable for plan years that begin on or after January 1, 2018. State Exchanges that choose to maintain their current operations may continue establishing enrollment timelines, as State law and SHOP technology permit. We also proposed that the requirements to transmit enrollment information on behalf of qualified employers and employees to QHP issuers as described in current paragraph (c), and to process payments as described in current paragraph (d) would not apply after plan year 2017, since SHOPs may not have enrollment or payment information to transmit. We proposed that the requirement in paragraph (e) that SHOPs ensure a QHP issuer notifies a qualified employee enrolled in a QHP of the effective date of his or her coverage would not apply

for plan years beginning on or after January 1, 2018 because SHOPs may not have the enrollment information necessary to enforce this requirement. We anticipated QHP issuers will notify employees in accordance with applicable State law. Additionally, after plan year 2017 plans have ended, we proposed not to require SHOPs to reconcile enrollment information as described in paragraph (g), as SHOPs may not have enrollment files to reconcile with issuers. We also proposed that the requirements described in current paragraph (h), which requires a SHOP to notify a qualified employee's employer in the event the qualified employee terminates his or her SHOP coverage, would no longer apply for plan years beginning on or after January 1, 2018. Under the proposed approach, SHOPs may not have that information to communicate to the qualified employee's employer.

We are finalizing these policies as proposed. These changes will become effective as of the effective date of the final rule. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

g. Record Retention and IRS Reporting for Plan Years Beginning on or After January 1, 2018 (§ 155.721)

The approach we are finalizing will not require SHOPs to provide functionality related to enrollment of employees for plan years beginning on or after January 1, 2018, and therefore, we proposed that § 155.720 be inapplicable for those plan years, effective on the effective date of this rule. However, there are requirements in that section related to record retention and IRS reporting that will continue to be applicable with some modifications. We proposed to include modified versions of these requirements in a new § 155.721, titled ''Record retention and IRS Reporting for plan years beginning on or after January 1, 2018.''

We proposed that all SHOPs still be required to maintain records of employer eligibility for 10 years, as described in paragraph (f). Because SHOPs utilizing the proposed flexibilities, like the FF–SHOPs, would not have information on employees, we did not propose to continue requiring that SHOPs maintain information on employees.

Section 155.720(i) describes the information a SHOP is currently required to communicate to the IRS for purposes of the Small Business Health Care Tax Credit. We proposed to modify the reporting requirement for SHOPs such that for plan years beginning on or after January 1, 2018, effective on the effective date of this final rule, SHOPs would be required to send the IRS information about the employers determined eligible to purchase a SHOP QHP only upon the request of the IRS. We stated that we believe providing the IRS with a list of employers determined eligible to participate in a SHOP, at the IRS's request, fulfills HHS's reporting responsibility. As mentioned earlier in this document, employers in all States must be able to provide sufficient evidence to the IRS that they meet all the necessary eligibility requirements for the Small Business Health Care Tax Credit, if they intend to apply for it. The IRS may ask employers to produce the aforementioned evidence and employers have a responsibility to produce it. Further, we stated that employers may work with their issuer to verify their contribution information, employee enrollment information, and any other applicable information required to apply for the Small Business Health Care Tax Credit through their tax filings.

We are finalizing these policies as proposed.

Comment: Commenters were generally supportive of these proposals. One commenter disagreed with the premise of this section, citing their lack of support for the overall proposed approach to allow SHOPs to operate in a leaner fashion. We also received a comment supporting the proposals to require SHOPs to only report information to the IRS as requested. This commenter sought clarification on whether HHS will continue to collect SHOP enrollment data per § 155.1200, which was addressed earlier in this rule at the beginning of section III.D.9. Finally, one commenter expressed concern about an employer's access to claim the Small Business Health Care Tax Credit if an employer is in a county where no SHOP plans are available. The commenter noted that in the past, the IRS has granted flexibility to employers in counties that had no SHOP plans available and allowed employers to still claim the Small Business Health Care Tax Credit, if otherwise applicable.

Response: We are finalizing this section as proposed. As noted above, we believe that the information being collected under our proposals and communicating that information only as requested by the IRS is sufficient for the purposes of their administration of the Small Business Health Care Tax Credit. The Treasury Department and the IRS have jurisdiction over the Small Business Health Care Tax Credit.

h. Enrollment Periods Under SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.725)

As discussed in the following section, we proposed to modify the regulatory requirements regarding enrollment periods under a SHOP for plan years beginning on or after January 1, 2018, and to introduce those requirements in a new § 155.726. To reflect the proposal that the requirements currently in § 155.725 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.725 and add paragraph (l), to state that the section would only apply for plan years that begin prior to January 1, 2018. These changes would become effective as of the effective date of the final rule. We discuss the proposed new § 155.726 below.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

i. Enrollment Periods Under SHOP for Plan Years Beginning on or After January 1, 2018 (§ 155.726)

Section 155.725 describes enrollment periods under SHOP, including the timeline under which employer groups must enroll in SHOP coverage, and the notices the SHOP is required to send related to enrollment periods. We proposed to introduce a new § 155.726, which would retain the rolling enrollment and minimum participation rate provisions of § 155.725(b) and (k), but would remove the requirements applicable to enrollment periods under SHOP other than those related to special enrollment periods for plan years beginning on or after January 1, 2018, to reflect the increased flexibility we proposed. The policies described in this section were proposed to be effective on the effective date of this rule.

Section § 155.725(a) requires that SHOPs ensure that enrollment transactions are sent to QHP issuers and that issuers adhere to coverage effective dates in accordance with this section. We proposed that many previously required enrollment and election periods would no longer apply for plan years beginning on or after January 1, 2018. State Exchanges that continue to provide online enrollment functionality for their SHOP will be able to continue to adhere to these requirements. However, under the proposed approach, some SHOPs (including the FF–SHOPs) may not have enrollment information to communicate to the issuers and may not want to continue setting and enforcing coverage effective dates under the

previously specified requirements. In SHOPs that pursue the full extent of the proposed approach, like the FF–SHOPs, we anticipated that most enrollment timelines, deadlines, and coverage effective dates in SHOPs would be set by employers and issuers consistent with applicable State law and otherwise applicable Federal law. We stated that we did, however, believe that, under the proposed approach, the SHOP should be responsible for ensuring that QHP issuers adhere to the remaining required enrollment periods and their corresponding coverage effective dates. Therefore, we proposed to include this requirement in § 155.726(a).

Paragraph (c) of § 155.725 states that the SHOP must provide qualified employers with an annual election period prior to completion of the employer's plan year and paragraph (d) of § 155.725 requires the SHOP to provide notice of that period in advance. Given that, under the proposed approach for SHOPs for plan years beginning on or after January 1, 2018, SHOPs would not be required to process enrollments, we proposed that these requirements would not apply for plan years beginning on or after January 1, 2018. We anticipated that participating QHP issuers in SHOPs pursuing the proposed approach, like in the FF–SHOPs, would be responsible for setting any requirements around renewals, annual employer election periods, and annual employee open enrollment periods, based on their current practices, and subject to applicable State law and otherwise applicable Federal law, including §§ 147.104 and 147.106. For similar reasons, we proposed that the requirements in § 155.725(e), which requires the SHOP to set a standard open enrollment period for qualified employees, and § 155.725(f), which requires the SHOP to send a notice to the employee about the open enrollment period, would not apply for plan years beginning on or after January 1, 2018.

Section 155.725(g) requires SHOPs to establish and maintain enrollment and coverage effective dates, including waiting periods, for newly qualified employees. However, the amendments we proposed at § 155.716 would remove the requirement for SHOPs to perform employee eligibility determinations, accept and process single employee SHOP application forms, as well as verify employee eligibility for plan years beginning on or after January 1,2018. Furthermore, our proposed amendments not to include paragraphs (c) and (d) of § 155.725 in § 155.726 would remove the requirement for SHOPs to maintain enrollment records for plan years beginning on or after January 1, 2018. SHOPs that utilize these proposed flexibilities, like the FF–SHOPs, may be unable to satisfy the requirements in § 155.725(g). To align with these proposed amendments, we proposed that the requirements in § 155.725(g) would not apply for plan years beginning on or after January 1, 2018. Instead, we anticipated that enrollment timelines, deadlines, and coverage effective dates for newly qualified employees in SHOPs that pursue the proposed approach would be set by employers and issuers consistent with applicable State law and otherwise applicable Federal law, including § 147.116. Further, as noted above, issuers offering plans in SHOPs would still be required to adhere to the guaranteed availability requirements set in § 147.104(b)(1)(i) and the special enrollment period requirements in proposed § 155.726(c).

We also proposed that the requirement in § 155.725(h)(1) that a SHOP establish the effective dates of coverage for initial and annual group enrollments would not apply for plan years beginning on or after January 1, 2018. Because SHOPs utilizing the proposed flexibilities, like the FF–SHOPs, would no longer be involved in processing group enrollments, and would therefore not be able to hold issuers accountable to these enrollment deadlines, we stated that we believed it was more appropriate to permit QHP issuers in SHOPs to set their own enrollment timelines. However, State Exchanges would be permitted to continue establishing these effective dates for their SHOPs. We also proposed to remove paragraph (h)(2) for plan years beginning on or after January 1, 2018, which establishes the effective dates for initial and annual group enrollments in FF–SHOPs, because the FF–SHOPs would utilize the proposed flexibilities. We anticipated that issuers in SHOPs that pursue this approach, like in FF–SHOPs, would set enrollment timelines for employer groups participating in these SHOPs, based on their current practices, and consistent with the market rules set forth in §§ 147.104 and 147.106, and otherwise applicable State law.

We proposed that the special enrollment periods specified in § 155.725(j) would continue to be applicable in the SHOPs for plan years beginning on or after January 1, 2018, and proposed to include these in § 155.726(c). We also proposed that the requirements regarding special enrollment periods in § 155.725(j)(3) would apply for plan years beginning on or after January 1, 2018. However, we proposed to modify the SHOPs' responsibilities with respect to special enrollment periods. As stated earlier in this preamble, under the new flexibilities for SHOPs beginning in plan years starting on or after January 1, 2018, SHOPs would no longer be required to provide functionality related to enrollment of employees. For SHOPs that pursue this flexibility, like the FF–SHOPs, issuers will preliminarily be responsible for completing enrollments, and so we expected issuers would implement enrollment periods. Therefore, we proposed to modify the requirements to reflect that the SHOP's revised role would not be to provide special enrollment periods, but to ensure that QHP issuers offering coverage through the SHOP provide the special enrollment periods set forth in regulation.

We are finalizing these policies as proposed, with one minor non-substantive change to correct the placement of numbering in the regulation text.

Comment: Some commenters requested clarification on our proposals at § 155.726(c), and recommended that the proposals better align with § 155.420, while another recommended that issuers be permitted to provide the same special enrollment periods as they provide outside the SHOP.

Response: Special enrollment periods offered through a SHOP are aligned with the special enrollment periods available in the individual market FFEs unless the special enrollment periods offered in the FFEs do not practically apply in the SHOP. We did not propose any changes to special enrollment periods in SHOPs and finalize this section as proposed.

j. Application Standards for SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 155.730)

As discussed in the following section, we proposed to modify the regulatory requirements regarding application standards of a SHOP for plan years beginning on or after January 1, 2018 and to introduce those requirements in a new § 155.731. To reflect the proposal that the requirements currently in § 155.730 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 155.730 and add paragraph (h), to state that the section would apply for only plan years that begin prior to January 1, 2018.

We are finalizing these policies as proposed; the policies will be effective on the effective date of the final rule. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

k. Application Standards for SHOP for Plan Years Beginning on or After January 1, 2018. (§ 155.731)

Section 155.730 describes the requirements for employer and employee applications in the SHOPs. We proposed to modify these requirements for plan years beginning on or after January 1, 2018, and to introduce these modified requirements in § 155.731. With the exception of the proposed changes to the requirements described here, the requirements would remain the same as in § 155.730.

In accordance with our approach allowing SHOPs to operate in a leaner fashion for plan years beginning on or after January 1, 2018, effective as of the effective date of this rule, QHP issuers would complete the process of enrolling qualified employees into coverage in SHOPs that will operate in a leaner fashion, like the FF–SHOPs. In those SHOPs it would not be necessary for a SHOP to collect information necessary for purchasing coverage. Therefore, we proposed to modify the information collection requirements related to the single employer application to require SHOPs to collect only information that would be necessary for SHOPs to determine employer eligibility to participate in the SHOP under § 155.710(b). To more closely align the description of the data elements collected with those standards for eligibility to participate, we proposed to require the SHOP to collect the employer name and address of the employer's locations; information sufficient to confirm that the employer is a small employer; the Employer Identification Number; and information sufficient to confirm that the employer is offering, at a minimum, all full-time employees' coverage in a QHP through a SHOP. SHOPs could collect other information, at their option subject to the limitations in § 155.716(c)(2) and § 155.731(f).

Paragraph (c) of § 155.730 requires the use of a single employee application. We proposed that this requirement would not apply for SHOP beginning for plan years starting on or after January 1, 2018, as the information collected in this application would no longer be necessary, since the SHOP would no longer be required to process employees' enrollment.

Section 155.730(d) permits a SHOP to use a model single employer application and model single employee application provided by HHS, and § 155.730(e) permits the use of HHS-approved alternatives to these model applications. We also proposed to maintain these options, but for consistency with the new approach to SHOP, we proposed not to reference a model single employee application. The model single employer application with the elements described in proposed § 155.731(b) has been updated to reflect these changes.[59]

Paragraph (g) of § 155.730 describes additional application safeguards for SHOP employer and employee applications, which we proposed to maintain in § 155.731(f) with minor amendments to reflect the proposal to eliminate the requirement to collect a single employee application. We also proposed in new paragraph (g) to state that § 155.731 would only be applicable for plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed. These changes will become effective as of the effective date of this rule.

Comment: One commenter expressed concern that our proposals to approve alternative applications will be burdensome, since applications are reviewed by the State.

Response: Section 155.731(b) discusses the application an employer submits to the SHOP for the purposes of determining eligibility to participate in a SHOP. No State review is required under § 155.731(b) (although a State Exchange could perform such a review, at its option, for its SHOP). The information that SHOPs are required to collect under these rules is minimal. HHS does not believe that additional information to determine an employer's eligibility to participate in a SHOP is necessary, and therefore maintains the ability to review any alternate application a SHOP may use to determine an employer's eligibility to participate in a SHOP. This section is being finalized as proposed.

Comment: We received one comment requesting clarification that State Exchanges can meet § 155.731(e)(2) by making an application available for download on a website as opposed to implementing an interactive web application portal.

Response: Section 155.730(e)(2) does not currently distinguish whether an employer application be available for download on an internet website as opposed to through an interactive web application portal on an internet website, so long as the tools to file an application be available on an internet website. We did not make any changes to this language in § 155.731(e)(2).

[59] Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/SHOP-Eligibility-Determination-Form.pdf.*

l. Termination of SHOP Enrollment or Coverage (§ 155.735)

Section 155.735 outlines requirements related to terminations of SHOP coverage or enrollment. Under our proposed approach, described in detail in the preamble to earlier sections of this final rule, the process of completing enrollments, as well as terminating coverage, could be completed by issuers, and would not be required to be completed by SHOPs operating in a leaner fashion under the flexibilities provided for in this rule, like the FF–SHOPs. Issuers would be expected to comply with otherwise applicable State and Federal law regarding terminating coverage, the timelines and effective dates for termination, and any notice requirements, including those at §§ 147.106 and 156.285. Accordingly, we proposed that this section would be applicable for only plan years beginning prior to January 1, 2018, as described in the proposed amendment to the heading and new paragraph (h), effective on the effective date of this rule. SHOPs maintaining current enrollment functions were encouraged to set termination guidelines and distribute notices for terminations based on nonpayment of premiums or loss of employee eligibility, unless State law requires QHP issuers to send the notices. Because SHOPs, such as the FF–SHOPs, would no longer be required to enroll groups into a SHOP QHP, they would no longer be required to maintain the ability to terminate coverage. We believe new §§ 155.716 and 157.206 sufficiently address terminations of eligibility for participation in a SHOP.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

m. SHOP Employer and Employee Eligibility Appeals Requirements for Plan Years Beginning Prior to January 1, 2018 (§ 155.740)

As discussed in the following section, we proposed to modify the regulatory requirements regarding employer and employee eligibility appeals in SHOP for plan years beginning on or after January 1, 2018, and to introduce those modified requirements in a new § 155.741. To reflect the proposal that the requirements currently in § 155.740 would apply only for plan years beginning before January 1, 2018, effective on the effective date of this rule, we proposed to amend the heading of § 155.740 and add paragraph (p), to state that the section would apply only

for plan years that begin prior to January 1, 2018.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

n. SHOP Employer and Employee Eligibility Appeals Requirements for Plan Years Beginning on or After January 1, 2018 (§ 155.741)

Section 155.740 describes the SHOP eligibility appeals process for employers and employees. These provisions describe the applicable definitions, the general requirements to provide for appeals, and employers' and employees' rights to appeal an eligibility determination from the SHOP.

To continue to provide for employer eligibility appeals, we proposed to add new § 155.741, mirroring § 155.740, with the following exceptions. Because we proposed elsewhere that the requirement to provide employees with eligibility determinations and the requirement in § 155.715(f) regarding notification of employee eligibility would no longer apply in plan years beginning on or after January 1, 2018, we proposed not to include a paragraph mirroring § 155.740(d), which describes employees' rights to appeal. We also proposed to omit other references to employee appeal rights, to add references to provide for appeals of terminations of eligibility to participate in a SHOP, and to update cross-references as applicable.

We proposed in paragraph (o) that the provisions of § 155.741 would only be applicable to plan years beginning on or after January 1, 2018, effective on the effective date of this rule.

We are finalizing these policies as proposed. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

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

1. FFE and SBE–FP User Fee Rates for the 2019 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the PPACA 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 PPACA directs HHS to operate an Exchange within the State. Accordingly, in § 156.50(c), we specified that a participating issuer offering a plan through an FFE or SBE–FP 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 and SBE–FPs 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 or SBE–FP.

OMB Circular No. A–25R establishes Federal policy regarding user fees; it 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. As in benefit years 2014 through 2018, issuers seeking to participate in an FFE in the 2019 benefit year 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 for the 2019 benefit year 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; and
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification).

OMB Circular No. A–25R further states that user fee charges should generally be set at a level that is 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). 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.

Based on estimated contract costs, enrollment and premiums for the 2019 benefit year, we proposed to maintain the 2019 benefit year user fee rate for all participating FFE issuers at 3.5 percent of total monthly premiums. We sought comment on this proposal.

State Exchanges on the Federal platform enter into an agreement with HHS to leverage the systems established for 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 specified 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 monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for SBE–FPs for the applicable benefit year, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or State instead of direct collection from the SBE–FP issuers. The benefits provided to issuers in SBE–FPs by the Federal government will include use of 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 PPACA, and enrollment in QHPs under § 155.400. As previously discussed, OMB Circular No. A–25R established Federal policy regarding user fees, and specified 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 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 infrastructure, and eligibility and enrollment functions, and allocating a share of those costs to issuers in the relevant SBE–FPs. A significant portion of expenditures for FFE functions 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 PPACA, and personnel who perform the functions set forth in § 155.400 to facilitate enrollment in QHPs. Based on this methodology, 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 plans offered through an SBE–FP. This fee would support FFE operations associated with providing the functions described above. We sought comment on this proposal.

We are finalizing the FFE and SBE–FP user fees rates at 3.5 and 3.0 percent

of monthly premiums, respectively, as proposed.

As we describe elsewhere in this rule, for plan years beginning on or after January 1, 2018, effective on the effective date of this rule, we are removing employee eligibility, premium aggregation, and online enrollment functionality through the FF–SHOPs for FFE and SBE–FP SHOP issuers. Given the changes to the functionality for the FF–SHOPs, HHS will not provide these special benefits through the FF–SHOPs or SBE–FP SHOPs after the effective date of the rule. Therefore, we proposed that HHS would not assess a user fee on issuers offering QHPs through FF–SHOPs or SBE–FP SHOPs because these user fees are only charged to issuers who receive special benefits from enrolling individuals through the Federal platform. In instances where enrollment did occur through the Federal platform, for example, for plan years beginning prior to the effective date of the final rule, HHS will continue charging SHOP issuers monthly FFE or SBE–FP user fees, as applicable. We are finalizing this policy as proposed.

Comment: Commenters noted the FFE user fee rate should decrease over time, particularly given the reduction in outreach and education activities that HHS conducts. Additionally, commenters noted that the collection and allocation of the user fees should be made more transparent. Other commenters also noted that HHS should allocate a greater portion of the user fees to outreach and education programs.

Response: The FFE and SBE–FP user fee rates for the 2019 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE–FPs and evaluation of expected enrollment and premiums for the 2019 benefit year. These estimates yielded an FFE user fee rate of 3.5 percent of premiums and an SBE–FP user fee rate of 3.0 percent of premiums. We reiterate that under OMB Circular No. A–25R, collections are only spent on user fee eligible activities. We will continue to examine cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE–FPs for future benefit years. Additionally, outreach and education efforts will be evaluated annually and funded at the appropriate level.

Comment: Some commenters did not support the proposed SBE–FP user fee rate, stating the proportion of FFE costs allocated to SBE–FP functions do not represent market value, the fee is overstated particularly in context of reduced outreach and education functions by the Federal platform, and increased premiums due to cost-sharing reductions amounts loaded to silver premiums ought to also reduce the user fee rate. Some of these commenters also stated that HHS has not provided SBE–FPs with enrollment data or access to *HealthCare.gov* back-end customer tools that the SBE–FPs could use to improve outreach and enrollment activities at the State level. Commenters suggested that HHS maintain the 2018 benefit year SBE–FP user fee rate of 2 percent given the impact of user fee rates on market premiums.

Response: The final SBE–FP user fee rate for the 2019 benefit year of 3.0 percent of premiums is based on HHS's calculation of the percent of contract costs of the total FFE functions utilized by SBE–FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs. We have calculated the total costs allocated to SBE–FP functions and enrollment and premium estimates to yield a user fee rate of 3.0 percent for SBE–FP issuers benefiting from functions provided by the Federal platform. We believe issuers offering QHPs through the Federal platform, either the FFEs or SBE–FPs, ought to be charged proportionally for the special benefits provided by the Federal platform. HHS has provided SBE–FPs 2 years to transition to the full rate. Additionally, although HHS reduced its outreach and education costs, we do not charge SBE–FPs for these costs as outreach and education activities are SBE–FPs' responsibility, and therefore the proportion of Federal platform costs associated with SBE–FP functions increased slightly compared to prior years. We also continuously collaborate with our SBE–FP partners to share data within our information disclosure agreements, and welcome continued conversations with SBE–FPs on their data needs.

Comment: Commenters also noted that HHS setting the SBE–FP user fee rate at 3 percent requires State entities to operate a referral hotline, consumer assistance, QHP rate review and certification, legal and finance operations, auditing and other functions with collections based on a State user fee rate of 0.5 percent of premiums, which would not be feasible, or require SBE–FPs to increase assessments on carriers. Commenters noted keeping a lower user fee rate for the SBE–FP model would likely increase States' take-up of these models and enrollment due to the resulting slightly lower increase in premiums.

Response: As we have previously stated, we are not requiring SBE–FPs to allocate a certain share of the State's assessments on various functions, and we are not requiring the SBE–FPs to set the State assessment at any specific rate. If SBE–FP States require more than 0.5 percent of premiums to carry out State functions for the 2019 benefit year, one option for the SBE–FP States could be to assess a higher State charge on issuers, and another option is for the SBE–FP States to assess a charge more broadly on issuers rather than just on issuers offering QHPs on the respective SBE–FPs. We are setting the 2019 SBE–FP user fee rate at 3.0 percent of premiums charged on participating issuers in SBE–FPs to recover the proportion of costs to the Federal government for the benefits associated with SBE–FPs, as required under OMB Circular No. A–25R. We continue to encourage and support States in pursuing the SBE–FP model, in assessing charges on participating issuers, or otherwise, to recover the costs associated with the State's functions and most effectively carry out those functions. We do not believe the total Federal charge assessed on FFE issuers are appropriately compared to the total State and Federal charge assessed on SBE–FP issuers because SBE–FPs provide the benefit of more proximately engaging issuers and consumers.

2. Essential Health Benefits Package

Section 2707(a) of the PHS Act, as added by the PPACA, directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which is defined under section 1302(a) of the PPACA to include coverage that provides for the EHB defined by the Secretary under section 1302(b) of the PPACA; limits cost sharing in accordance with section 1302(c) of the PPACA; and provides either the bronze, silver, gold, or platinum level of coverage, or is a catastrophic plan under sections 1302(d) and (e) of the PPACA. Section 1302(b) of the PPACA states that the Secretary is to define EHB, except that EHB must include at least the following general categories and the items and services covered within the categories: (1) Ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease

management; and (10) pediatric services, including oral and vision care. Additionally, section 1302(b)(2) of the PPACA states that the Secretary must ensure that the scope of EHB for the 10 EHB categories be equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary. Furthermore, section 1302(b)(2) of the PPACA states, in defining and revising EHB, that the Secretary is to submit a report to the appropriate committees of Congress containing a certification from the CMS Chief Actuary that such EHB are equal in scope to the benefits provided under a typical employer plan. In defining and revising the 10 EHB categories, the Secretary must also provide notice and an opportunity for public comment. Additionally, section 1302(b)(4)(G) and (H) of the PPACA require the Secretary to periodically review and update the definition of EHB and provide a report to Congress and the public that contains assessments related to the need to update the definition of EHB.

Section 1302(b)(4) of the PPACA requires the Secretary, in defining the EHB, to: (1) Ensure that such EHB reflect an appropriate balance among the categories so that benefits are not unduly weighted toward any category; (2) not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life; (3) take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups; (4) ensure the health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life; and (5) provide that a QHP shall not be treated as providing coverage for EHB unless it meets certain requirements for coverage of emergency services.

To implement section 1302(b) of the PPACA, HHS defined EHB based on a benchmark plan approach, which provided at § 156.100 for the States' selection from one of 10 base-benchmark plans, including the largest health plan by enrollment in any of the three largest small group insurance products by enrollment, any of the largest three employee health benefit plan options by enrollment offered and generally available to State employees in the State, any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits-eligible Federal employees under 5 U.S.C. 8903, or the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State. States were required at § 156.110 to supplement their base-benchmark plan from § 156.100 to ensure the 10 EHB categories were being covered to establish the State's EHB-benchmark plan. Section 156.110 also ensures that the EHB-benchmark plan meets the standards of nondiscrimination and balance of benefits, and allows habilitative services to be determined by the State.

We believe that States should have additional choices with respect to benefits and affordable coverage. As such, we proposed to provide States with additional flexibility in their selection of an EHB-benchmark plan for plan year 2019 and later plan years. In addition to granting States more flexibility regulating their markets, we believed these changes would permit States to modify EHB to increase affordability of health insurance in the individual and small group markets beginning in 2019. We proposed that the current EHB-benchmark plan selection would continue to apply for any year for which a State does not select a new EHB-benchmark plan under this proposal.

In the preamble of the proposed rule, we stated that we were considering establishing a Federal default definition of EHB for plan years further in the future that would allow States continued flexibility to adopt their own EHB-benchmark plans, provided they defray costs that exceed the Federal default. We understood that in developing this type of default definition there are trade-offs in adjusting benefits and services. We gave an example of establishing a national benchmark plan standard for prescription drugs that could balance these tradeoffs and provide a consistent prescription drug default standard across States. We solicited initial comments on this type of long-term approach and the trade-offs in adjusting benefits from the current EHBs with a plan to solicit further comments in the future.

Comment: Many commenters requested more detail on a Federal default definition of EHB, with some commenters suggesting the publication of a white paper to discuss such a policy in more detail.

Most commenters opposed a Federal default definition of EHB. Many commenters were concerned that a Federal default definition of EHB would be implemented in the pursuit of seeking arbitrary benefit limits, even at the cost of inferior health outcomes.

Some commenters expressed concern over diminishing the State's flexibility in defining their own EHB, especially since other proposals with regard to EHB concentrated on giving additional flexibility to the States. These commenters also expressed concern over requiring States to defray the costs of benefits in excess of a Federal standard.

Many commenters expressed support for a Federal default EHB definition if such a standard represented a minimum level of benefits required in an EHB-benchmark plan, rather than a maximum level of benefits. Commenters noted that plans should include a wide array of benefits to account for the diverse needs of the population at large. Other commenters supported a Federal default EHB definition to the extent that certain benefits would be included in such a definition.

Most commenters opposed a Federal default definition of EHB as it pertains to a national prescription drug benefit, noting that States and issuers are best positioned to evaluate and respond to prescription drug needs. Many of these commenters expressed concerns similar to those raised regarding a general Federal default EHB definition: Concerns that such a standard would, in the pursuit of arbitrary benefit limits, have a negative impact on health outcomes by inhibiting the availability of needed drugs; establish a maximum level of benefits for EHB-benchmark plans; diminish the States' flexibility to define EHB; and increase the defrayals required by States.

Some commenters noted that a national prescription drug benefit standard would require continuous and frequent updating to account for changes in clinical guidelines and drug innovation. These commenters supported a national prescription drug benefit standard that uses a qualitative approach reliant upon Pharmacy & Therapeutics Committees to respond to such rapid changes, rather than a standard based on providing a minimum number of drugs per category or class.

A few commenters supported a national prescription drug benefit, noting that multi-State issuers face complexity dealing with minimum drug counts which vary widely across EHB-benchmark plans, with no rational medical justification for the variation.

Some commenters expressed concern about the impact of a Federal prescription drug benefit on the ability

of entities to negotiate drug prices. One commenter noted that a Federal default EHB definition for prescription drugs would stifle innovation due to uncertainty over whether a new drug would be covered.

Response: Our intention is to better align medical risk in insurance products by balancing costs to the scope of benefits. We will take these comments under consideration as we consider this policy. In order to avoid market instability and inefficiencies for States that have used the expanded flexibilities regarding EHB that we are finalizing in this rule and issuers in those States, it is our intent that any Federal default standard would not require a State to make immediate changes to its EHB-benchmark plan within 3 years following a State change.

a. State Selection of Benchmark Plan for Plan Years Beginning Prior to January 1, 2020 (§ 156.100)

To reflect the proposed options in § 156.111 for States to adopt new EHB-benchmark plans for plan years 2019 and later, we proposed to make conforming changes to § 156.100 to explicitly state that the selection process in § 156.100 applies only through plan years beginning in 2018, and § 156.111 applies for plan years beginning after 2018. Because we are finalizing § 156.111 to apply for plan years 2020 and later, we are not finalizing these conforming changes as proposed, but are instead making changes to § 156.100 to state that the selection process in § 156.100 applies only through plan years beginning in 2019, and § 156.111 applies for plan years beginning on or after January 1, 2020.

Comment: A few commenters commented on the proposal to make conforming changes to § 156.100 as a result of our proposed changes to § 156.111. These commenters generally did not support the proposed policy of § 156.111 and supported retaining the current benchmark plan options at § 156.100 that provided benchmark plan options at the State level.

Response: Since we are finalizing the new options for a State's EHB-benchmark plan at § 156.111 starting for plan year 2020, we are finalizing conforming changes to § 156.100, to reflect § 156.111.

b. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

i. States' EHB-Benchmark Plan Options (§ 156.111(a))

We proposed to add new § 156.111, which would provide States with the flexibility to update their EHB-benchmark plans more frequently and to select among more options. Specifically, we proposed that a State may change its EHB-benchmark plan by: (1) Selecting the EHB-benchmark plan that another State used for the 2017 plan year[60] under § 156.100 and § 156.110; (2) replacing one or more EHB categories of benefits under § 156.110(a) in its EHB-benchmark plan used for the 2017 plan year with the same categories of benefits from another State's EHB-benchmark plan used for the 2017 plan year under § 156.100 and § 156.110; or (3) otherwise selecting a set of benefits that would become the State's EHB-benchmark plan, provided that the EHB-benchmark plan does not exceed the generosity of the most generous plan among a set of comparison plans. Under this third option, the comparison plans would be the State's EHB-benchmark plan used for the 2017 plan year and the plans described in § 156.100(a)(1) for the 2017 plan year, supplemented as necessary under § 156.110. These plans would include the largest health plan by enrollment in each of the three largest small group insurance products by enrollment from the State's 2017 base-benchmark plan options.[61] Under any of the available three options, we proposed that a State could change its EHB-benchmark plan in any given year, not only in the years that HHS specified. At the same time, this proposed policy would also allow States that prefer to maintain their current EHB-benchmark plans to do so without action.

Option 1: Select Another State's EHB-Benchmark Plan

Under the first option, we proposed that a State be permitted to select one of the EHB-benchmark plans used for the 2017 plan year by another State. We did not propose to change the State mandate policy at § 155.170 under this option. Under this proposed policy, we proposed that benefits mandated by State action prior to or on December 31, 2011 could continue to be considered EHB under § 155.170, and would not require the State to defray the costs. Conversely, if a State selects an EHB-benchmark plan from another State using this option, the selecting State would still be required to defray the cost of any benefits included in that State's EHB-benchmark plan that are benefits mandated by the selecting State after December 31, 2011, and that are subject to defrayal under the current regulations.[62] For example, if State A selects the EHB-benchmark plan of State B, State A would be required to defray the cost of any benefits included in State B's EHB-benchmark plan that are required to be provided by State A's action after December 31, 2011, and that are subject to defrayal under current regulations. We solicited comments on this proposal, including on the application of the State mandate policy under this proposal and on whether other flexibilities are needed by States under this proposed option.

Option 2: Replace Category or Categories From Another State's EHB-Benchmark Plan

Under the second option, we proposed that a State be allowed to partially replace its current EHB-benchmark plan, using EHB-benchmark plans used by other States for the 2017 plan year. Under this option, we proposed that a State may replace any EHB category or categories of benefits in its EHB-benchmark plan from the 10 required EHB categories with the same category or categories of benefits from another State's EHB-benchmark plan used for the 2017 plan year. For example, a State may select the prescription drug coverage from another State's EHB-benchmark plan (which might include a different formulary drug count) and a third State's EHB-benchmark plan hospitalization category. Similar to the first option, we proposed that benefits mandated by State action prior to or on December 31, 2011, could continue to be considered EHB under this proposal in accordance with § 155.170, and would not require the State to defray their costs. However, if a State uses this option to replace one or more categories of its EHB-benchmark plan used for the 2017 plan year with a category or categories of benefits from another State's EHB-benchmark plan used for the 2017 plan year, the selecting State would be required to defray the cost of any benefits included in the categories of benefits from the other State's EHB-benchmark plan that are mandated by the selecting State's action after

[60] The States' EHB-benchmark plans used for the 2017 plan year are based on plans from the 2014 plan year, but we occasionally refer to them as 2017 plans because these plans are applicable as the States' EHB-benchmark plans for plan years beginning in 2017.

[61] The Essential Health Benefits: List of the Largest Three Small Group Products by State for 2017 is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Top3ListFinal-5-19-2015.pdf.* States' EHB-benchmark plans used for the 2017 plan year are able at *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-BMPs_4816.pdf.*

[62] Under § 155.170, the State must make payments to defray the cost of additional required benefits either to an enrollee, as defined in § 155.20, or directly to the QHP issuer on behalf of the enrollee.

December 31, 2011 and that are subject to defrayal under current regulations. For example, if State A replaces a category of benefits in its EHB-benchmark plan with a category of benefits from State B's EHB-benchmark plan, State A must defray the cost of any benefits in that category mandated by State A after December 31, 2011 that are included in the replacement category of benefits and that are subject to defrayal under current regulations.

Option 3: Select a Set of Benefits To Become the State's EHB-Benchmark Plan

Lastly, under the third option, we proposed that a State be permitted to select a set of benefits that would become its EHB-benchmark plan using a different process, so long as the new EHB-benchmark plan does not exceed the generosity of the most generous among a set of comparison plans. Under this option, the set of comparison plans would be the State's EHB-benchmark plan used for the 2017 plan year and the plans described in § 156.100(a)(1) that were available as base-benchmark plan options for the 2017 plan year, supplemented as necessary under § 156.110. These plans would include the largest health plan by enrollment in each of the three largest small group insurance products by enrollment from the State's base-benchmark options for the 2017 plan year. We proposed that the State would determine if its proposed EHB-benchmark plan does not exceed the generosity of the most generous of a set of comparison plans using an actuarial certification, developed by an actuary who is a member of American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies. For this actuarial certification, we proposed that the State could determine generosity in the same manner as we would use to measure whether the plan provides benefits that are equal in scope of benefits provided under a typical employer plan, described later in this section.

We also recognized that the increased flexibility offered to States under this proposed option to define an EHB-benchmark plan could allow a State to embed any desired benefit mandate into the EHB-benchmark plan, without any requirement to defray the obligation. For this reason, we proposed to apply the benefit mandate defrayal policy under § 155.170 to this option. Specifically, we proposed that benefits mandated by State action prior to or on December 31, 2011 could continue to be considered EHB under this proposal according to § 155.170, and would not require State defrayal. However, if a State selects its EHB-benchmark plan using this option, the State must continue to defray the cost of any benefits mandated by State action after December 31, 2011 that are subject to defrayal under current regulations. For example, if the State selects a set of benefits to become its EHB-benchmark plan under paragraph (a)(3), any benefits mandated by that State after December 31, 2011 that are subject to defrayal under current regulations would not be considered EHB, and the State would be required to defray the cost of any such benefits included in the State's EHB-benchmark plan under this proposed option.

We solicited comments on all of the proposals, including on whether to allow a State to select its EHB-benchmark plan from any of the 10 previous base-benchmark plan options available to the State or other States under § 156.100, supplemented as necessary under § 156.110, on whether a different approach is needed to defray the cost of any benefits mandated by State action, on whether other flexibilities are needed by States under the proposed options, on our proposed approach to limit a State's new EHB-benchmark plan under Option 3, such that it does not exceed the generosity of the comparison plans, and on whether other options should be provided to States to select their EHB-benchmark plans beyond the three proposed options. We are finalizing these new EHB-benchmark plan options as proposed, with one amendment. As further discussed in the comments and responses below, we are extending the proposed requirements at § 156.111(a)(3)(i) and (ii) that ensure that the State's new EHB-benchmark plan does not exceed the generosity of the most generous among a set of comparison plans to all of the State's options to select a new EHB-benchmark plan at § 156.111(a). We are finalizing these requirements at § 156.111(b)(2)(ii).

Comment: Some commenters supported the proposed EHB-benchmark plan options for States because they offer increased State flexibility through additional options for States. Many commenters did not support the proposed EHB-benchmark plan policy or supported retaining the current policy, and noted that it already allows State flexibility. Many of these commenters were concerned that States would decrease EHB benefits as a result of the proposed policy, or that issuers would not cover benefits that are not EHB. Some commenters were concerned that the options would create a patchwork of benefit designs that could diminish care, increase or shift costs or affect issuer competition.

Other commenters believed that the proposed policy was inconsistent with the statutory requirements that the Secretary define EHB and that the Secretary ensure other EHB consumer protections under section 1302(b)(2), (3), and (4) of the PPACA are incorporated into the definition of EHB. These commenters believed that the Secretary has no authority to delegate defining EHB or its parameters to States or issuers. Commenters also believed that the proposed options allowed States to select an EHB-benchmark plan from among an endless set of options, whereas the prior policy allowed a preset list of 10 plan options per State, with most options being from the State in which the plan was applying. Some commenters also believed that the proposed policy was inconsistent with the statutory requirement that the Secretary update EHB based on gaps in coverage or changes in the evidence identified in the Secretary's report to Congress as established at section 1302(b)(4)(H) of PPACA. Some of these commenters also noted that this report has not been completed.

Response: As described in the EHB Final Rule, we originally established the benchmark plan policy to ensure that EHB is equal to the scope of benefits provided under a typical employer plan and in recognition that the typical employer plans differ by State. Specifically, the Secretary balanced these directives, and minimized market disruption, by directing plans to offer the 10 statutory EHB categories while allowing the State to select the specific details of their EHB coverage from a set of reference plans. Accordingly, States maintained their traditional role in defining the scope of insurance benefits and exercised that authority by selecting a plan that reflects the benefit priorities of that State, within the bounds of the definition of EHB set by the Secretary.[63] This deference to States within the definition established by the Secretary continues under the policies finalized in this rule.

We believe that States should have additional choices with respect to benefits, which may foster innovation in plan design and greater access to coverage, and provide States with a mechanism for affecting affordability. This approach may balance these considerations in manners different from the balance achieved under the previous benchmark plans. The Secretary is defining an expanded set of options from which the State can select

[63] EHB Rule, 78 FR at 12843. February 23, 2013.

its EHB-benchmark plan, allowing the State to select the specific details of that plan. This policy recognizes the need for increased State flexibility beyond that which the original policy allowed.

For this reason, we are finalizing the new options for a State's EHB-benchmark plan, along with additional requirements for the State's selection as detailed later in this preamble. We believe these requirements, when taken together, provide States with significant flexibility while appropriately limiting the range of choices, thereby fulfilling the Secretary's obligation to define EHB. Specifically, the requirement that a State's EHB-benchmark plan provide a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, as defined at § 156.111(b)(2), establishes a minimum scope of benefits that is required to be covered as EHB. Furthermore, the requirement that the EHB-benchmark plan cannot exceed the generosity of the most generous among a set of comparison plans, which are those group market plans that comprise the basis for the scope of benefits under the current definition of EHB, further limits the range of benefits that can be considered EHB. Together with the other requirements specified at § 156.111(b)(2), these requirements provide States with flexibility to adjust their States' EHB-benchmark plan within a limited range.

At the same time, this policy also allows a State to retain its current EHB-benchmark plan. This flexibility was not afforded under the previous policy. In fact, the previous default option, which was the largest plan by enrollment in the largest product by enrollment in the State's small group market, could vary between benchmark plan selection years, creating unnecessary disruption for States that were unable to select a benchmark plan. Under the new policy, these States, as well as States that do not wish to make changes, will not be required to do so, and will not need to take action to prevent the disruption caused by a change to the State's EHB-benchmark plan.

We are not completing the report to Congress and the public on the periodic review of EHB under section 1302(b)(4)(G) of the PPACA at this time. We do not believe that a report on EHB at this time will provide conclusive results on the assessments required under section 1302(b)(4)(G) of the PPACA, as a large portion of plans required to comply with EHB are QHPs offered both on and off of the Exchanges. These QHP markets have seen significant changes from year to year since their inception, with the number of issuers offering plans in each market changing on an annual basis and the number of enrollees in these plans fluctuating. Furthermore, the frequent modifications to EHB policies and other related Federal benefit policies, such as guidance on complying with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and preventive services regulations, have not allowed these plans' benefit structures to stabilize enough for conclusive analysis. Since the PPACA only requires this report to Congress to be conducted periodically, and we do not believe that conducting this report at this time will establish meaningful conclusions, this report will not be completed at this time. We intend to conduct this report once the market has stabilized, which we believe will be furthered by the policy we are finalizing in this rule.

Comment: Many commenters were concerned that the proposed EHB-benchmark plan options would create a race to the bottom among States' scope of benefits for their EHB-benchmark plans. These commenters were especially concerned that these benefit designs would not meet the needs of vulnerable populations, would increase costs to consumers, and would reduce the value of coverage. Some commenters were concerned that benchmark plans selected under one of the first two options would not reflect plans in the State or meet the needs of beneficiaries in that State. Some commenters were concerned that these proposed options discourage States from selecting more generous coverage, with some commenters stating that if the true goal of the policy was to increase State flexibility, the State should also have the option to increase benefits.

Other commenters were concerned that the first two options allow States to pick more generous plans, and some commenters recommended preventing States from being able to select an option without being responsible for the costs of the additional benefits. In general, these commenters were concerned that the proposed policy would allow States to select benchmark plans with more generous State mandates. Other commenters were concerned that there is significant variation in benchmark plan coverage of particular services, and some commenters stated that the goal of allowing State flexibility should be secondary to ensuring comprehensiveness of the benefit package.

Other commenters noted that the second option allows the State to define EHB by selecting the least generous benefits for each category, thus creating a standard that does not resemble any existing plan in the market today. Commenters were similarly concerned that the third option could allow a State to greatly reduce the generosity of coverage, even though the definition would still require the coverage of the 10 EHB categories. Some commenters were concerned that the third option was too broad and did not ensure consumer protections to ensure the comprehensive scope of benefits.

Response: We are not persuaded that the new options will create a race for States to establish the least generous plan possible because all States' EHB-benchmark plans will be required to include coverage for all 10 EHB categories of benefits, and the State will be required to confirm its EHB-benchmark plan includes coverage for each EHB category in accordance with § 156.111(e)(1). Section 156.111(e)(1) also requires States to confirm that its new EHB-benchmark plan meets the applicable requirements of § 156.111(b) on scope of benefits, including that the State's EHB-benchmark plan provide a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan in accordance with § 156.111(e)(2).[64] Through those requirements, the options at § 156.111(a) do not allow a State to substantially reduce the level of coverage, and instead allow a State the option to adjust its EHB-benchmark

[64] We are also retaining the current issuer requirements related to EHB at §§ 156.115, 156.122, and 156.125 and those requirements would continue to apply to all plans subject to the EHB requirements. This includes 45 CFR 156.122(a)(1) that establishes that, generally, a health plan does not provide EHB unless it covers at least the greater of: (1) One drug in every USP category and class; or (2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. Under the current version of the USP Medicare Model Guidelines (MMG) drug classification system used for the EHB drug count at § 156.122(a)(1), this proposal means that all plans required to comply with EHB will continue to have to cover at least one drug in the Anti-Addiction/Substance Abuse Treatment Agents (Opioid Reversal Agent) class. Naloxone is currently the only active ingredient in the Opioid Reversal Agent class, and as a result all plans required to comply with EHB would be required to continue to cover at least one form of naloxone under this proposed policy. This was previously addressed in the 2018 Letter to Issuers in the Federally-facilitated Marketplaces available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces-and-February-17-Addendum.pdf.*

plan to use benefit structures that have worked well in other States or other parts of the employer markets, or otherwise innovate benefits within the range of plans in the employer market. Because each State has different market conditions and demographic distributions, a plan that may be the least generous plan in one State may not be the least generous plan in another State, and for that reason, we are not concerned that this policy is going to create a race to establish the least generous plan.

In short, this flexibility established under § 156.111(a) is not intended to reduce benefits, but to allow for more innovative benefits within the current benefit requirements. This means that a State's EHB-benchmark plan may not have the exact same benefits and limits as the typical employer plan the State identifies under this policy, but this policy will still result in the State's EHB-benchmark plan providing a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, satisfying the Secretary's obligations at section 1302(b) of the PPACA. Furthermore, as described later in this rule, we are finalizing a definition of a typical employer plan that requires the plan have enrollment and be sold in the State. This definition ensures that regardless of the benchmark plan option selected by the State under this rule, that benchmark plan will be at least equal to the scope of benefits to a popular employer plan that was previously offered in the State's employer plan market.

Furthermore, we encourage States to select EHB-benchmark plans that foster innovation in plan design that would provide greater access to coverage that would ultimately improve affordability. As discussed in the proposed rule, in addition to granting States more flexibility in regulating their markets, one of the goals with this policy was to permit States to modify EHB to increase affordability of health insurance in the individual and small group markets.[65] As we also note in our discussion of benefits mandated by State action at § 155.170, we want to ensure that States do not select EHB in a manner that decreases affordability of coverage. Therefore, in response to commenters' concerns about ensuring that the options under § 156.111(a) do not undermine the goal of affordability, we are incorporating into the regulation protections to ensure that a State's EHB-benchmark plan selections take into account affordability of coverage, by applying the generosity test proposed in connection with the third option to all three EHB-benchmark plan selection options for States. Accordingly, § 156.111(b)(2)(ii) provides that a State may not select a new EHB-benchmark plan that exceeds the most generous among a set of comparison plans, no matter the option used to generate the EHB-benchmark plan. These comparison plans include the State's EHB-benchmark plan used for the 2017 plan year and the plans described in § 156.100(a)(1) for the 2017 plan year, supplemented as necessary under § 156.110.[66] We recognize that it may be possible for a State's EHB-benchmark plan to provide a scope of benefits that is equal to (or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a)) the scope of benefits provided under a typical employer plan at § 156.111(b)(2)(i), and not meet the generosity standard at § 156.111(b)(2)(ii) (for example, a proposed EHB-benchmark plan could satisfy the typical employer plan requirement but exceed the generosity standard because of the way supplementation was performed). However, we believe that by extending this generosity limit to all selection options, we are minimizing the opportunity for a State to select EHB in a manner that would make coverage unaffordable for patients and increase Federal costs, while still helping to ensure that States are ensuring that benefits are equal to the scope of benefits provided under a typical employer plan.

Comment: Some commenters were concerned that a State would have difficulty knowing what another State's EHB-benchmark plan was covering, because the benefits or benchmark plan documentation were not broken into separate EHB categories. Some commenters were generally concerned about using the 2017 EHB-benchmark plans. These commenters noted that States are only supplementing categories of benefits in those plans when those categories are missing and are not considering the scope of benefits within the category, leading to inadequate coverage. Other commenters wanted to understand how supplementation would work under the options.

Response: Additional supplementation of the EHB-benchmark plans generally should not be required under the three State EHB-benchmark plan selection options being finalized at § 156.111(a). For the first option at § 156.111(a)(1), the selecting State would be selecting another State's EHB-benchmark plan, which already would be supplemented, as necessary.[67] For the second option at § 156.111(a)(2), the State would replace a category or categories of benefit from its current EHB-benchmark plan with another State's EHB-benchmark plan's category or categories of benefits, which already would have been supplemented, if necessary, by that other State.

A State using the third option will need to ensure that its EHB-benchmark plan satisfies the requirements being finalized at § 156.111(b), such as the requirements to cover items and services in each of the ten statutory categories of EHB; to not have benefits unduly weighted towards any of those categories of benefits; and to provide a scope of benefits equal to (or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a)), the scope of benefits provided under a typical employer plan. Since States have been supplementing their EHB-benchmark plans since the inception of the EHB policy, we expect States to be familiar with categorizing benefits.

Comment: Various commenters supported coverage of specific services within an EHB category, with some commenters noting that many of the services that might be considered for reduction are only a small portion of spending. They stated that not covering these services would not meaningfully reduce premiums and would increase or shift costs for the services for the consumers who need them. Other commenters noted that all of the options are linked in part to the 2017 EHB-benchmark plans (including the generosity standard under Option 3), and that these are in fact 2014 plans. Certain commenters were concerned

[65] 82 FR at 51102.

[66] The actual number of comparison plans for each State depends on the State's EHB-benchmark plan for 2017. Most States will only have three comparison plans as the State's EHB-benchmark plan for 2017 is a plan within the options at § 156.100(a)(1). However, a few States will have four comparison plans as the State's EHB-benchmark plan for 2017 is not a plan within the options at § 156.100(a)(1). The list of plan options at § 156.100(a)(1) for each State for 2017 is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Top3ListFinal-5-19-2015.pdf.* Also, the States' EHB-benchmark plans used for the 2017 plan year are available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-BMPs_4816.pdf.*

[67] Information on whether the State supplemented its EHB-benchmark plan for 2017 is available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/Final-List-of-BMPs_4816.pdf.*

that these 2014 plans do not comply with new requirements, such as the applicability of requirements under MHPAEA or noted that using 2014 plans in the long term means that EHB would still be linked to 2014 plans. Comments varied on whether States that are selecting an EHB-benchmark plan should be allowed to select from any States' previous EHB-benchmark plans for options § 156.111(a)(1) or (2). A few commenters recommended that HHS give States additional technical assistance. For example, one commenter sought clarification on which State entity would be authorized to select the State's EHB-benchmark plan. Certain commenters also had concerns about provider discrimination under the proposed policy.

Response: Because § 156.111 continues to define EHB based on a ''benchmark plan'' approach, we are continuing the policy of not requiring that a State's EHB-benchmark plan cover a specific service or services or use particular providers. We are limiting the policy to the 2017 EHB-benchmark plans under Options 1 and 2 at § 156.111(a)(1) and (2) to ensure that the set of plans available for States to select from under Option 1 and 2 are clearly defined and reflect an EHB-benchmark plan that was used by another State. We believe that this policy balances providing flexibility to States to select from more options for their EHB-benchmark plans while at the same time providing simplification of choice within a defined set of plan options. Furthermore, this policy will not overly limit State flexibility, as the third option would permit a State to select from any of the other 10 previous base-benchmark plan options. While the 2017 EHB-benchmark plans and the benchmark plans selected by States under § 156.111(a)(3) may not comply with all of the market reforms and consumer protections applicable to plans offered in the individual and small group markets, this is not a departure from the benchmarks that have been used to date. We reiterate the policy that non-grandfathered insurance plans in the individual and small group markets that are required to comply with EHB must not only provide benefits that are substantially equal to the EHB-benchmark plan, but must also comply with all Federal requirements applicable to plans offered in those markets, such as those benefit requirements at §§ 156.115, 156.122, 156.125, and 156.130(g).

We also recognize that States have different processes for selecting a benchmark plan and as a result, the State needs discretion in determining what entity has the authority to select the State's EHB-benchmark plan. We therefore will not dictate which State entity must act to select a State's EHB-benchmark plan, but we may consider providing States with additional technical assistance to aid in their selection under the policy finalized in this rule.

Comment: Many commenters were concerned about the impact of the proposed policy on the determination of which benefits are subject to the prohibition of annual and lifetime dollar limits in section 2711 of the PHS Act, as added by the PPACA, and the annual limitation on cost sharing at section 1302(c) of the PPACA (which is incorporated into section 2707(b) of the PHS Act). Some commenters were particularly concerned about the impact of this policy on markets beyond the Exchanges, particularly the large group market and self-insured group health plans. These plans are not required to provide coverage of EHB but must use a definition of EHB to determine which benefits apply to the prohibition of annual and lifetime dollar limits and the annual limitation on cost sharing. These commenters were generally concerned about increased or shifting costs to consumers for benefits that are no longer EHB, particularly for vulnerable populations. Some commenters were concerned that since large group market and self-insured group health plans could use any State's definition of EHB for purposes of the annual and lifetime dollar limit prohibition and the annual limitation on cost sharing, any State's definition could have the potential to impact plans nationwide. Other commenters wanted additional information and evaluation of the impact on how the change in definition would be implemented.

Response: As discussed in more detail earlier in this section, the flexibility established under § 156.111(a) is not intended to reduce benefits, but to allow for more innovative benefits within the current benefit requirements. This means that a State's EHB-benchmark plan may not have the exact same benefits and limits as the typical employer plan the State identifies under this policy, but this policy will still result in the State's EHB-benchmark plan providing a scope of benefits that is equal to, or greater than, the scope of benefits provided under a typical employer plan in accordance with § 156.111(b)(2)(i), satisfying the Secretary's obligations at section 1302(b) of the PPACA. Accordingly, we do not expect that there will be a substantial change to the scope of the protections afforded under the annual and lifetime dollar limit prohibition or the annual limitation on cost sharing.

ii. The Requirements for States' EHB-Benchmark Plans (§ 156.111(b) Through (d))

Under the proposed options for States to select a new EHB-benchmark plan, we proposed that a State's EHB-benchmark plan must meet certain requirements established under the PPACA with regard to EHB coverage, scope of benefits, and notice and opportunity for public comment. First, under paragraph (b)(1), we proposed to require that the State's EHB-benchmark plan provide an appropriate balance of coverage for the 10 EHB categories of benefits as established at § 156.110(a) and under section 1302(b)(1) of the PPACA. Second, we proposed at paragraph (b)(2) to define requirements regarding the scope of benefits that must be provided by a State's EHB-benchmark plan. Specifically, we proposed at paragraph (b)(2)(i) that the State's EHB-benchmark plan must be equal in scope of benefits to what is provided under a typical employer plan. This proposed requirement reflects section 1302(b)(2) of the PPACA, which requires the Secretary to ensure that the scope of the EHB is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary. We proposed to define a typical employer plan as an employer plan within a product (as these terms are defined in § 144.103 of this subchapter) with substantial enrollment in the product of at least 5,000 enrollees sold in the small group or large group market, in one or more States, or a self-insured group health plan with substantial enrollment of at least 5,000 enrollees in one or more States. We sought comment on many parts of this definition, including:

- Whether the definition of a typical employer plan should reflect in substantial part a plan that would be typical in the State in question;
- Whether an appropriate way to measure typicality in that case would be to provide that the typical employer plan be defined to also have at least 100 enrollees enrolled in that plan or product in the applicable State;
- Whether typicality should be defined in other ways, including whether it should be based upon the State's 10 base-benchmark plan options for plan year 2017, supplemented as required to become the State's EHB-benchmark plan under § 156.110;
- Whether the definition of a typical employer plan for this purpose should be limited to plans that already cover all 10 EHB categories;

• Whether the proposed typical employer plan definition should exclude self-insured plans, since States may not have the ability to obtain the required information on those plans; and

• Whether we should provide additional guidance or requirements for the definition of a typical employer plan, such as requiring that the plan selected as a typical employer plan be from a recent year after December 31, 2013, requiring that the plan provide minimum value, or requiring that the plan selected as a typical employer plan not be an indemnity plan or an account-based plan like a health reimbursement arrangement.

Given that the proposed definition of a typical employer plan was a plan with enrollment of at least 5,000 enrollees in one or more States, we believed that the State's option to select another State's EHB-benchmark plan at proposed § 156.111(a)(1) would automatically meet the typical employer plan requirement because each of the available options is an employer plan that had substantial enrollment.

We also solicited comment on whether actuaries could develop a standard of practice for a benefit comparison calculation to determine that a plan is equal to the scope of benefits provided under a typical employer plan that could also apply to determine that a State's EHB-benchmark plan does not exceed the generosity of the most generous plan in accordance with the third option under proposed § 156.111(a)(3). We specifically sought comment on our draft example of an acceptable methodology for comparing benefits of a State's EHB-benchmark plan selection to the benefits of a typical employer plan.[68]

In addition to meeting the typical employer plan requirements, we proposed at paragraph (b)(2)(ii) that the State's EHB-benchmark plan must also not have benefits unduly weighted towards any of the categories of benefits at § 156.110(a) as established under section 1302(b)(4)(A) of the PPACA. Furthermore, we proposed at paragraph (b)(2)(iii) that the State's EHB-benchmark plan must provide benefits for diverse segments of the population, including women, children, persons with disabilities, and other groups as established under section 1302(b)(4)(C) of the PPACA.

At paragraph (c), we proposed that the State must provide reasonable public notice and an opportunity for public comment on the State's selection of an EHB-benchmark plan. We proposed that this process would apply whenever a State changes its EHB-benchmark plan in accordance with proposed § 156.111(a).

Lastly, we proposed at paragraph (d) that a State must notify HHS of the selection of a new EHB-benchmark plan by a date to be determined by HHS for each applicable plan year. We also proposed that if the State does not make a selection by the annual selection date, the State's EHB-benchmark plan for the applicable plan year would be that State's EHB-benchmark plan applicable for the prior plan year. Taken together, these proposed requirements were intended to align with statutory requirements. We affirmed that §§ 156.115, 156.122, and 156.125 would continue to apply to all plans subject to the EHB requirements.

We are finalizing the requirements for a State's EHB-benchmark plan with certain amendments to: (1) Clarify that the State's EHB-benchmark must provide coverage of items and services for at least the 10 EHB categories; (2) add a codification of the currently applicable requirement at § 156.110(d) that the State's EHB-benchmark plans must not include discriminatory benefit designs that contravene the non-discrimination standards defined in § 156.125; (3) modify the definition of a typical employer plan; (4) add a requirement that the State must post a notice of its opportunity for public comment with associated information on a relevant State website; (5) provide that any State EHB-benchmark plan may be no more generous than the most generous among a set of comparison plans, as described above; and (6) codify in regulation text the proposed standard in the preamble of the proposed rule that if a State's benchmark plan selection does not meet the requirements of this section and section 1302 of the PPACA, the State's EHB-benchmark plan will be the State's EHB-benchmark plan applicable for the prior year, as further described under the data collection section below. To reflect the application of the generosity standard to all three options under this regulation, we moved that provision from § 156.111(a)(3) to § 156.111(b)(2), and have renumbered parts of § 156.111(b)(2) for clarity.

Comment: Many commenters stated that the definition of EHB provides important protection to consumers, particularly with regard to various populations. Some commenters appreciated the codification of certain EHB protections under section 1302(b) of the PPACA into the regulation text, with some requesting the non-discrimination provisions from section 1302(b) of the PPACA be included, too. Some commenters wanted strong Federal enforcement of EHB requirements, such as non-discrimination. Some commenters believed that the standards were too vague or wanted additional guardrails on States' EHB-benchmark plans. A few commenters wanted certain clarifications to § 156.111(b)(1), such as the inclusion of items and services or on requiring coverage of the 10 EHB categories.

Response: In the proposed rule, we did not propose to eliminate the EHB-benchmark plan standards under § 156.110. However, we recognize based on comments that the applicability of that section to benchmark plans selected under the proposed § 156.111 was not as clear as it could have been. Therefore, in response to commenters, we are finalizing § 156.111(b) with certain amendments that align with the statute and that clarify the applicability of EHB-benchmark plan standards. We are amending § 156.111(b)(1) to more explicitly state that the EHB-benchmark plan must not only provide an appropriate balance of coverage of the 10 statutory categories of EHB, but also cover items and services in all 10 categories.

We are also adding a new § 156.111(b)(2)(v) to codify the continuing applicability of the currently applicable benchmark plan non-discrimination provisions under § 156.110(d) to the EHB-benchmark plan selection options under § 156.111(a). Specifically, a State's EHB-benchmark plan may not violate the non-discrimination standards defined in § 156.125, which reflects the non-discrimination provisions of section 1302(b)(4) of the PPACA.

Comment: Many commenters opposed allowing States to annually update their EHB-benchmark plans. These commenters had a variety of concerns about annual updates to the benchmark plans, such as annual updating would be administratively and financially burdensome to issuers, confusing for consumers, lack predictability, or would create instability that would not allow issuers to assess the effectiveness of previous changes before new changes are implemented. Some commenters recommended limiting the changes to every few years, with some supporting every 3 years, which aligns with the

[68] The *Draft Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection to Benefits of a Typical Employer Plan As Proposed under the HHS Notice of Benefit and Payment Parameters for 2019 (CMS–9930–F)* is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Example-Acceptable-Methodology-States-EHB.pdf.*

frequency with which the benchmark plans have previously been updated. Some commenters recommended timeframes for the State's annual submission process, such as requiring the EHB-benchmark plans to be finalized 18 months prior to the benefit year, to help ensure that issuers have sufficient time to design products in advance of the filing deadlines for the upcoming benefit year.

Response: As discussed in the proposed rule, we recognize the burden on States and issuers of making changes to a State's EHB-benchmark plan. Specifically, we anticipated most States would need to invest resources to analyze the three new EHB-benchmark plan selection options to make an informed selection, even if a State defaults. We also anticipated that issuers offering plans that provide EHB would incur additional administrative costs associated with designing plans compliant with the State's newly selected EHB-benchmark plan.[69] Because of the level of effort needed by the State and its issuers to make changes to a State's EHB-benchmark plan, we believe that in only very limited cases will a State choose to make EHB-benchmark plan changes on an annual basis. We believe that if a State does decide to make changes annually, there may be a specific reason for needing an annual change such as for a medical innovation where such benefits would outweigh any potential for consumer confusion. We also do not believe that such changes would rise to the level of creating market instability. The purpose of this policy is to allow for State flexibility in selecting an EHB-benchmark plan, and we believe it is important for States to retain the flexibility to choose when the State wants to make changes to its EHB-benchmark plan. Therefore, we are finalizing the policy as proposed.

As described in the next section, we are finalizing the 2020 deadline for submission of a State's EHB-benchmark plan under § 156.111(a). For plan years after 2020, we intend to announce the annual EHB-benchmark plan selection deadline to States in the annual notice of benefits and payment parameters. Because we expect that the number of submissions for each plan year will vary, we will not be providing a specific date as to when the State's EHB-benchmark plans for a given plan year will be finalized.

Comment: Many commenters opposed allowing the definition of typical employer plan to include self-insured plans, as these plans can have unique benefit designs, and are not directly regulated by States, and because it would be difficult to obtain plan information for such plans. Some commenters stated that the lack of specificity in the definition of a typical employer plan could allow rare, outlier plans with extremely limited coverage to become the typical employer plan, or they requested that there be additional requirements on the typical employer plan to prevent outlier plans from being the typical employer plan. Commenters were concerned that the definition could jeopardize adequate coverage of the 10 EHB categories, lowering the threshold for minimum coverage, or allowing insurers to offer plans with less generous benefits, weakening the PPACA protections for individuals with disabilities and complex medical needs.

Some commenters were particularly concerned that the policy in the proposed rule generally focused on using the definition of EHB to create a ceiling for the scope of benefits. They expressed concern that the generosity standard limits the scope of benefits to certain previous benchmark plan options, instead of providing the floor for the scope of benefits, as they stated PPACA intended the definition of EHB to be. These commenters were concerned that decreased benefits would result in high costs for consumers to access those services.

Some commenters wanted more specificity in the definition of typical employer plan, such as wanting the plan to be specific to the State to ensure compatibility in the State or meet State requirements, be required to cover all 10 EHB categories or minimum benefit standards, be from a recent plan year, constitute MEC, provide minimum value (or some other actuarial value standard), not be an account-based plan, not be a preventive-services-only plan or an excepted benefit plan or not be an indemnity plan. Some commenters supported the definition of a typical employer plan for its flexibility or supported aspects of the proposed definition. Another commenter noted that if a State-specific enrollment requirement is added, current EHB-benchmark plans under the first option may not automatically meet the definition.

Commenters recommended different enrollment thresholds for the typical employer plan, with some commenters noting that substantial enrollment varies by State or the lack of justification for the 5,000 enrollee threshold. Other commenters believed that the proposed policy disregarded the concept of typicality as being the scope of coverage typically seen in employer-based plans or did not believe enrollment should be an indicator for typicality (as typicality is about comparability and enrollment is about size).

Response: We agree with commenters that the definition of EHB should establish a minimum level of benefits. In response to commenters' concerns with the proposed definition of typical employer plan, we are finalizing two sets of typical employer plans from which a State may choose for purposes of ensuring a minimum scope of benefits for the State's EHB-benchmark plan, which establishes the State's EHB definition.

First, we are finalizing that the typical employer plan may be one of the selecting State's 10 base-benchmark plan options established at § 156.100 from which the State could select for the 2017 plan year. This definition, which allows the selecting State to continue to select from its previous options, will allow a selecting State to modify its previous base-benchmark plan options to innovate those benefits to better meet the needs of consumers in its market.

Second, we are finalizing that a typical employer plan also may be the largest health insurance plan by enrollment in any of the five largest large group health insurance products by enrollment in the selecting State, as product and plan are defined at § 144.103, provided that: (1) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products by enrollment in the selecting State; (2) the plan provides minimum value, as defined under § 156.145; (3) the benefits are not excepted benefits, as established under § 146.145(b) and § 148.220; and (4) the benefits in the plan are from a plan year beginning after December 31, 2013.

For purposes of this definition, we are applying the Federal definitions of plan and product at § 144.103.[70] Under these definitions, the product comprises all plans offered with the same covered benefits and as a result, each plan within a product must have the same benefit package. To ensure that these plans are typical within the selecting State, the determination of each product's enrollment numbers is based on enrollment in the selecting State.

[69] 82 FR at 51131.

[70] Section 144.103 defines ''product'' as ''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'' and a plan as ''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.''

Also, to ensure that none of these products are outliers within the State, only plans from products that have at least 10 percent of the total enrollment of the five largest large group health insurance products can be selected. For example, if a selecting State's three largest large group health insurance products under the second definition at § 156.111(b)(2)(ii) have 92 percent of the enrollment in the selecting State among the five largest large group health insurance products in the State, the fourth and fifth largest large group health insurance products in the selecting State will not have at least 10 percent of the enrollment and therefore, will not be an option under the second prong of the typical employer plan definition. The use of enrollment size in defining the typical employer plan aligns with the previous policy where the base-benchmark plan options were also determined based on the enrollment in those markets. Furthermore, by using the largest products by enrollment in the selecting State, rather than on a specified enrollment size, we ensure that any variation in population size by the selecting State is taken into account. We believe this second prong of the definition provides States with important additional flexibility, as it expands the comparison options available to States when comparing their selected EHB-benchmark plan to a typical employer plan, while simultaneously ensuring the statutory requirement that the definition of EHB be equal in scope to a typical employer plan is met.

We agree with commenters that self-insured plans have a significantly greater likelihood of being plans with atypical benefit designs. Therefore, this definition for typical employer plan does not include self-insured plans, including health reimbursement arrangements. We also recognize that States would have challenges obtaining information about these other types of plans, especially at the level of detail needed for the plan to be used as a comparison to the State's EHB-benchmark plan. To limit the burden on States to determine which plans in the State would be included in the second set of plans, we are limiting the second set under the definition of typical employer plan to large group market health insurance plans and products.

In response to commenters who recommended that the typical employer plan be required to provide minimum value (MV), we are also finalizing as part of the second prong of the definition of the typical employer plan that the plan must meet MV requirements under § 156.145. Under § 156.145, an employer-sponsored plan provides minimum value only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan must include substantial coverage of inpatient hospital services and physician services, characteristics that we believe are reflective of typical employer plans. For example, by requiring the typical employer plan meet MV, outlier plans, such as preventive-services-only plans, which do not provide substantial coverage of inpatient hospital and physician services in accordance with the MV requirement, could not satisfy the second definition of typical employer plan.

To further respond to comments recommending that we ensure that outlier plans are excluded from the definition of typical employer plan, we are finalizing as part of the second prong of the definition a requirement that the plan's benefits are not excepted benefits, as defined under § 146.145(b), and § 148.220. For example, a worker's compensation plan would not meet the second prong of the definition of a typical employer plan. This requirement specifically ensures that the typical employer plan is a major medical plan. Lastly, we are requiring that the benefits in the plan are from a plan year beginning after December 31, 2013. This requirement is consistent with the options under the first prong of the typical employer plan definition, which references plans originally offered in 2014.

In applying the typical employer plan definition, we recognize that States may find that the plans that meet the definition of a typical employer plan may not provide coverage for items and services within each EHB category at § 156.110(a). Therefore, we are finalizing that the State's EHB-benchmark plan must provide a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan. The purpose of this approach is to permit States' EHB-benchmark plans' scope of benefits not to be equal to the benefits under the typical employer plan definition, only by exceeding the scope of benefits provided by the typical employer plan, and only if necessary to ensure that all EHB categories of benefits are being covered. We believe that these requirements, when taken together, ensure outlier plans are excluded from the definition of a typical employer plan, respond to commenters' concerns regarding the risk that the definition of typical employer plan would include atypical plans and ensure that the requirement for the EHB-benchmark plans' scope of benefits to be equal to that of a typical employer plan can account for benefits within each EHB category at § 156.110(a).

Comment: Some commenters believed that the statute requires that the scope of benefits for the typical employer plan be informed by the Department of Labor report [71] required under section 1302(b)(2)(A) of PPACA. These commenters did not believe that the proposed typical employer plan definition was informed by the 2011 DOL report and were concerned that defining the typical employer plan using enrollment instead of typicality of benefits allows skimpier benefits, which would have a detrimental effect on the most vulnerable enrollees in a way that contravenes the PPACA requirement and implicates the Americans with Disabilities Act. Some commenters were particularly concerned about the impact of the proposed typical employer plan definition under the third option and some commenters expressed concern about the potential scope of coverage under plans that meet the proposed definition. Some commenters expressed concern about coverage of benefits for specific groups, such as those with opioid use disorders.

Response: As required by section 1302(b)(2)(A) of the PPACA, the Department of Labor conducted a survey of employer-sponsored coverage and published a report on the survey on April 15, 2011. In determining what constitutes a typical employer plan, HHS reviewed and considered the findings of this survey. As discussed in more detail earlier in this section, the flexibility established under § 156.111(a) is not intended to reduce benefits, but to allow for more innovative benefits within the current benefit requirements. Similarly, with regard to comparing the scope of benefits of an EHB-benchmark plan to a typical employer plan, we note that the scope of benefits refers to the overall extent of benefits covered, not to the inclusion of any particular benefits. A State's EHB-benchmark plan is not required to cover a particular benefit because that benefit is part of the typical employer plan the State uses to assess the scope of benefits in its EHB-benchmark plan. Rather, the particular

[71] Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services. April 15, 2011. *https://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf.*

benefits and limitations in a State's EHB-benchmark plan are established through one of the options defined in §§ 156.100, 156.110 or 156.111 and the resulting EHB-benchmark plan provides a scope of benefits that is equal to, or greater than the scope of benefits that typical employer plan, as explained earlier in this preamble.

We encourage States to consider, as they select their EHB-benchmark plans, the potential impact on vulnerable populations, and the need to educate consumers on benefit design changes. Specifically, as States work to address the opioid crisis, we urge States to consider whether and how selecting a new EHB-benchmark plan could help address the crisis in their State.

Comment: Commenters generally supported requiring States to provide public notice and an opportunity for public comment on its selection of an EHB-benchmark plan, with some commenters supporting State flexibility to determine the process. Most commenters, on the other hand, wanted minimum or standardized requirements for the public comment process, such as requiring the solicitation of input from certain groups, a public hearing, a comment period of 30 days or 60 days, the posting of usable and understandable data, analysis and plan documents (such as the documentation to be submitted to HHS under § 156.111(e)), posting of any changes, a requirement that the State submit documentation on its public hearing process to HHS, or some combination of these standards. These commenters typically wanted a transparent process to ensure meaningful and equal participation of consumers, or wanted to reduce the burden of having a different process for each State. One commenter wanted the regulation to at least reference the State's applicable public comment period under the State's administrative procedure act or department of insurance rules while another was concerned that the rule assumes that a State has in place a reasonable public comment process. Some commenters supported requiring the State to post public notice while other comments wanted a process to identify inadequacies or appeal a State's decision.

Response: We agree with commenters that the State public notice and comment period is important for transparency to allow consumers to provide feedback on the States' proposed changes to their EHB-benchmark plans. However, we believe that States have varying processes for soliciting and receiving comments and may have used varying processes previously to provide public notice and an opportunity for public comment on their EHB-benchmark plan selections.

Therefore, in an effort to retain State flexibility under this requirement, with one exception, we are finalizing a policy under which States must provide reasonable public notice and opportunity for public comment, but will look to States to reasonably interpret that requirement. In response to comments, we are finalizing a requirement that the State, regardless of the public comment process it uses to select its EHB-benchmark plan, must post a notice on a relevant State website regarding the opportunity for public comment with associated information.

For States that do not have a public notice and comment process for these purposes, these States should consider using a similar process for public comment to the one established at § 155.1312(a)–(c). We also remind States that any public participation processes must continue to comply with applicable Federal civil rights laws, including those that require covered entities to provide meaningful access for individuals with limited English proficiency, and those that require effective communications for individuals with disabilities, including web accessibility requirements. The public notice process at § 156.111(c) applies whenever a State changes its EHB-benchmark plan in accordance with § 156.111(a).

iii. Data Collection for State's EHB-Benchmark Plans for 2020 Plan Year and Later (§ 156.111(e))

We proposed data collection requirements at § 156.111(e) for a State that opts to select a new EHB-benchmark plan under § 156.111(a) in any given year, beginning with the 2019 plan year. We proposed that a State must submit documents in a format and manner specified by HHS by a date determined by HHS and proposed four areas of documentation. First, at paragraph (e)(1), we proposed to require documentation that would confirm that the State's EHB-benchmark plan complies with the requirements under proposed § 156.111(a), (b) and (c), which includes the requirement that the 10 EHB categories of benefits are covered under the State's EHB-benchmark plan. This documentation would also include information on which selection option under proposed § 156.111(a) the State is using, including whether the State is using another State's EHB-benchmark plan.

Second, in paragraph (e)(2), we proposed, for a State selecting an EHB-benchmark plan under § 156.111(a)(2) or (3), that the State's documentation must include an actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, affirming that the State's EHB-benchmark plan is equal in scope of benefits provided under a typical employer plan. We proposed that if the State is selecting its EHB-benchmark plan using § 156.111(a)(3), which allows the State considerable flexibility to otherwise select a set of benefits that would become its EHB-benchmark plan, that the actuarial certification and associated report would also affirm that the new EHB-benchmark plan does not exceed the generosity of the most generous among the set of comparison plans specified in paragraph (a)(3). For the actuarial certification, we proposed that these documents, in accordance with generally accepted actuarial principles and methodologies, would include complying with all applicable Actuarial Standards of Practice (ASOP) (including but not limited to ASOP 41 on actuarial communications). We also sought comment on a draft methodology for comparing benefits of a State's EHB-benchmark plan selection to the benefits of a typical employer plan for the actuarial certification and associated actuarial report [72] and on whether the draft methodology should be the required approach for the State's actuarial certification and associated actuarial report.

Third, we proposed at paragraph (e)(3) that the State would be required to submit an EHB-benchmark plan document that reflects the benefits and limitations in the benchmark plan, including the medical management requirements, a schedule of benefits and, if the State is selecting its EHB-benchmark plan using the option in paragraph (a)(3), a formulary drug list in a format and manner specified by HHS similar to current § 156.120. For a State that chooses an EHB-benchmark plan under proposed § 156.111(a)(1), the State may submit the plan document from the other State's EHB-benchmark plan used for the 2017 plan year to fulfill this proposed requirement. For a State that selects an EHB-benchmark plan under proposed § 156.111(a)(2), the

[72] The *Draft Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection to Benefits of a Typical Employer Plan As Proposed under the HHS Notice of Benefit and Payment Parameters for 2019 (CMS–9930–F)* is available on CCIIO's Regulation and Guidance web page at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

State could create a combined plan document by assembling parts of the plan documents from the other State's or States' benchmark plan documents. We acknowledged that States may need to make conforming edits in the other States' plan documents to align language and terminology. For a State that chooses the option proposed at § 156.111(a)(3), the State may need to develop a plan document. Additionally, under proposed § 156.111(e)(3), if the State is selecting its EHB-benchmark plan using the option in § 156.111(a)(3), we proposed that the State must also include a formulary drug list for the State's EHB-benchmark plan in a format and manner specified by HHS. We also proposed that for a benefit, such as the pediatric dental benefit, that is defined by another program under the State's EHB-benchmark plan, the State may submit a separate document that reflects the benefits and limitations, including the medical management requirements and a schedule of benefits comparable to how States that defined their dental coverage using their State's CHIP programs have done previously. Otherwise, regardless of which option the State is using to select a new EHB-benchmark plan, the State would be expected to submit one comprehensive plan document for the entire State's EHB-benchmark plan selection.

Lastly, we proposed under paragraph (e)(4) to require the State to submit documentation specified by HHS, which is necessary to operationalize the State's EHB-benchmark plan. This documentation would be used to provide public resources on a State's EHB-benchmark plan and support related templates and tools. We proposed that this documentation would include a complete and accurate EHB summary chart that reflects the State's EHB-benchmark plan and aligns with the documentation that we currently make publicly available on a State's EHB-benchmark plan. For States that choose § 156.111(a)(1) or (a)(2) where the State is developing its benchmark plan based on another State's EHB-benchmark plan, the State could develop this document utilizing information from the EHB summary chart that is currently publicly available.[73]

We proposed that HHS would post the State's EHB summary document and the State's EHB-benchmark plan document on the Center for Consumer Information and Insurance Oversight (CCIIO) website. We also considered posting the State's EHB-benchmark plan confirmations proposed at § 156.111(e)(1).

We proposed that in order for a State's selection of a new EHB-benchmark plan from the proposed options to be accepted, the State's new EHB-benchmark plan must comply with the associated EHB regulatory and statutory requirements, including those under this final rule. If a State's EHB-benchmark plan selection does not meet these regulatory and statutory requirements, the State's current EHB-benchmark plan would continue to apply. We solicited comments on the proposed processes and deadlines for the 2019 and 2020 plan years.[74] We also solicited comments on the proposed data collection and associated documents and whether other specifications for these documents are needed. We are finalizing the provisions at § 156.111(e) with an amendment to § 156.111(e)(2) to reflect the changes to § 156.111(b)(2)(i) and (ii) described above. We are finalizing that the policy will begin applying for the 2020 plan year.

Comment: Commenters generally supported transparency in EHB-benchmark plan documents and making these documents publicly available. Some commenters noted concerns about the completeness and accuracy of current EHB-benchmark plan documents and the inconsistent level of detail among EHB summary charts, encouraging accuracy in plan information to limit confusion.

Response: Section 156.111(e) is designed to ensure that the State's EHB-benchmark plan meets the requirements at § 156.111(b), (c), and (d) and to ensure that the State's EHB-benchmark plan has a clearly defined set of covered benefits. In an effort to support transparency, we will post all documents[75] that a State submits pertaining to its EHB-benchmark plan selection on CCIIO's website with the exception of the drug list. These documents will include the State's confirmations (§ 156.111(e)(1)), any actuarial certification and associated actuarial report (§ 156.111(e)(2)), the plan documents (§ 156.111(e)(3)), and the documents necessary to operationalize the State's EHB-benchmark plan (§ 156.111(e)(4)). The State's EHB-benchmark plan drug list will be posted in the category and class count format in the EHB summary chart as the current drug counts are currently posted.[76]

Because EHB-benchmark plan benefits are based on plans that were sold in 2014, some of the benchmark plan documents may not comply with current Federal requirements. For this reason, the State confirmations require the State to confirm that its EHB-benchmark plan meets the requirements to be an EHB-benchmark plan. Since States are typically the primary enforcer of EHB policy, States may take varying approaches to the level of details included in the EHB Summary Chart, as we believe the manner in which the State displays the EHB-benchmark plan in the EHB Summary Chart may be reflective of the State's EHB enforcement strategies.

Furthermore, we also recognize that the States' 2017 EHB-benchmark plans may need conforming edits to comply with other laws and regulations, and to account for any benefits considered EHB under § 155.170. For these reasons, we clarified in the proposed rule that benefits and limits described in the available benchmark plan documents on our website may not be fully applicable due to other laws and regulations. For instance, under section 2711 of the PHS Act, as added by the PPACA, issuers may not impose lifetime or annual dollar limits on EHBs. When lifetime or annual dollar limits are specified in available EHB-benchmark plan documents, States would have removed the dollar limits or converted them to non-dollar limits when interpreting and applying EHB policy. HHS recognizes most States as the primary enforcers of EHB policy. Thus, when a State would use an EHB-benchmark plan that originated in another State under any proposals under § 156.111, we would generally defer to the selecting State's implementation of the benefits and limits consistent with otherwise applicable law, even when such interpretation differs from the originating State's interpretation. Where possible, States should provide clarity on benefits and limits in the documents collected under § 156.111(e) or note differences in the States' EHB summary chart.

Lastly, we are codifying in regulation text at § 156.111(d)(1) a proposed standard that we discussed in the preamble of the proposed rule, under which the State's new EHB-benchmark plan must comply with the regulatory

[73] All States' current benchmark plan documents are posted on CCIIO's website at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html.*

[74] For the 2019 plan year, HHS would post States' EHB-benchmark plan documents after the proposed State submission deadline, which would likely be in April 2018.

[75] CMS's PRA website is available at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

[76] *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html.*

and statutory requirements, including those under this final rule, in order for HHS to accept a State's selection of a new EHB-benchmark plan from the options under § 156.111(a). If a State's EHB-benchmark plan selection does not meet these regulatory and statutory requirements, the State's current EHB-benchmark plan would continue to apply.

Comment: Some commenters on the *Draft Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection to Benefits of a Typical Employer Plan As Proposed under the HHS Notice of Benefit and Payment Parameters for 2019 (CMS–9930–F)* did not support parts of the proposed methodological approach. Comments generally did not support the use of small group index rates or wanted an upper-bound limit of 98 percent to 102 percent for the category comparison, with some commenters, noting the difficulty in conducting this type of calculation or recommending additional input or more detail. Others wanted to require actuarial data from the States to justify adoption of a benchmark plan that varies significantly from their current benchmarks in any category. Comments on the actuarial certification and associated actuarial report requirements varied on which EHB-benchmark selection options it should apply to.

Response: To account for the application of the typical employer plan definition at § 156.111(b)(2)(i) and the generosity standard at § 156.111(b)(2)(ii) to all selection options, we are finalizing § 156.111(e)(2) with certain changes. Specifically, we are finalizing the requirement that States provide an actuarial certification and an associated report from an actuary from the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms: (1) That the State's EHB-benchmark plan provides a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan as defined at § 156.111(b)(2)(i); and (2) the State's EHB-benchmark plan does not exceed the generosity of the most generous among the set of comparison plans at § 156.111(b)(2)(ii)(A) and (B). States will be required to submit an actuarial certification and an associated report under § 156.111(e)(2) to affirm that both of the standards at § 156.111(b)(2)(i) and § 156.111(b)(2)(ii) are met, regardless of which selection option under § 156.111(a) they use.

The purpose of the policy being finalized at § 156.111 is to strike a balance between providing flexibility to allow States' additional options to select their EHB-benchmark plans and ensuring that States' EHB-benchmark plans meet the associated statutory requirements. To that end, the actuarial certification and associated actuarial report are intended to ensure that the scope of EHB is equal in scope to the benefits provided under a typical employer plan, and to provide the information to support the certification from the Chief Actuary of CMS for the Secretary to submit along with a report to Congress, consistent with section 1302(b)(2)(B) of the PPACA. Section 1302(b)(2)(B) of the PPACA requires that the Chief Actuary of CMS certify that the scope of EHB as defined by the Secretary is equal to the scope of benefits provided under a typical employer plan. Through this rule, the Secretary is determining that the actuarial certification and associated actuarial report at § 156.111(e)(2) ensures any EHB-benchmark plan selection is meeting the requirements at section 1302(b)(2)(A) of PPACA; therefore, we are finalizing these requirements.

This includes the requirement that the actuarial certification and associated actuarial report be prepared in accordance with generally accepted actuarial principles and methodologies. This includes all applicable ASOPs. For example, ASOP 41 contains disclosure requirements, including those that apply to the disclosure of information on the methods and assumptions being used and ASOP 50 contains information on determining MV and AV. In accordance with ASOP 41, we would expect that the actuarial report is based on a data analysis that is reflective of an appropriate population.

State actuaries may need flexibility in developing the actuarial certification and report depending on the type of changes that the State is interested in making to its EHB-benchmark plan and depending on the typical employer plan that the State is using for the certification and report. For these reasons, we are finalizing an example methodology with several changes.[77] First, to provide clarification for actuaries, we expanded the methodology to address the determination of the plan generosity under § 156.111(b)(2)(ii) in parallel to the determination of the typical employer plan, and further explained how an actuary could use a typical employer plan or a comparison plan for this certification and associated report.

Second, we are finalizing the definition of a typical employer plan to establish the minimum level of benefits for the State's EHB-benchmark plan and the generosity standard to establish the maximum level of benefits for a State's EHB-benchmark plan selection. By tying the maximum level of benefits, in part, to certain previous States' EHB-benchmark plan options, the new State EHB-benchmark plan selections are tied to generosity of the current EHB-benchmark plans in the States, which is not what a 102 percent upper bound limit would provide. For these reasons, we believe that creating an additional upper-bound limit under the typical employer plan in the example methodology is not necessary, would be duplicative, and would be difficult to implement with the generosity standard at § 156.111(b)(2)(ii).

Lastly, to support the use of more appropriate data for the actuarial certification and associated actuarial report, we removed the use of small group index rates from the calculation of the expected value. Instead, we provide other examples of acceptable data that an actuary may use, including data acquired from issuers in the State for a recent plan year, and weighted the services and benefits provided in each EHB category. We believe that the changes to the methodology will help inform actuaries on how to approach the actuarial certification and associated report at § 156.111(e)(2).

Comment: Commenters generally opposed implementing the new EHB-benchmark plan options for the 2019 benefit year. Some of these commenters were concerned about operational and administrative feasibility and burden to implement an EHB change for 2019, as well as the lack of adequate time to design products and meet 2019 rate and form filing deadlines. Other commenters were concerned about the ability for States and issuers to evaluate options, or the impact of the policy leading to market instability, increased costs, or consumer confusion. Some commenters noted that the goal of market stability was more important than the goal of providing States with added flexibility. Another commenter was concerned about the potential for data errors due to short timeframes.

Commenters generally supported making EHB-benchmark plan changes for the 2020 plan year at the earliest, with some noting that the 2020 timelines aligns with previous

[77] *Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii)* is available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

benchmark plan timelines. Certain commenters wanted additional analysis or information before implementing any change. Other commenters wanted to ensure that States provide outreach to consumers on the EHB-benchmark plan changes. A commenter wanted to understand how guaranteed renewability might affect changes to plans being made to reflect changes from a new State EHB-benchmark plan selection.

Response: We acknowledge the operational and administrative difficulties for States, issuers and consumers with implementing a changing benefit design under the timeframes for the 2019 benefit year, and believe that a 2020 implementation date would provide these stakeholders with additional time to ensure a smooth implementation of any benefit design changes. For these reasons, we will make § 156.111 effective for the 2020 plan year. We are also finalizing the deadline for State submission of its EHB-benchmark plan as July 2, 2018, for the 2020 plan year.[78] This deadline aligns with the timing of HHS's previous updates to the benchmark plans.

As for guaranteed renewability, under some circumstances, issuers may be permitted to change their products to reflect new requirements for providing EHB as uniform modifications of their products. Otherwise, if the changes to products are deemed to result in the removal of products from the market, issuers would be required to meet the product discontinuance requirements under § 147.106, which generally require at least 90 days advanced notice to the enrollees of the discontinuance.

c. Provision of EHB (§ 156.115)

Currently, to provide EHB, plans are required to provide benefits that are substantially equal to the EHB-benchmark plan. However, an issuer of a plan offering EHB may substitute benefits *within* categories, if allowed by the State, provided that the benefits are actuarially equivalent to the benefit that is being replaced. Substitutions of prescription drug benefits are not permitted.[79] In the EHB Rule, we finalized a policy at § 156.115(b)(1) under which substitution may not occur between different benefit categories.

In an effort to promote greater flexibility, consumer choice, and plan innovation through coverage and plan design options, we proposed modifying paragraph (b)(1)(ii) to allow States to permit issuers to substitute benefits within the same EHB category *and* between EHB categories, as long as the substituted benefit is actuarially equivalent to the benefit being replaced and is not a prescription drug benefit. The plan with substitutions would still be required to provide benefits that are substantially equal to the EHB-benchmark plan, to provide an appropriate balance among the EHB categories such that benefits are not unduly weighted towards any category, and to provide benefits for diverse segments of the population. It is generally the State's responsibility to assess that plans required to provide EHB adhere to these requirements.

We noted that nothing in this proposal would prohibit plans required to provide EHB from imposing non-dollar limits, unless otherwise prohibited by Federal law.[80] In addition, we noted that we would continue to defer to States, which have the option to set criteria for benefit substitution, to enforce a stricter standard on benefit substitution, or to prohibit it altogether consistent with paragraph (b) of this section. We sought comment on examples of substitution that issuers would be interested in pursuing.

We are finalizing the proposal with amendments to clarify when issuers may substitute benefits and States' roles in permitting or prohibiting substitution. Specifically, we are finalizing the change to allow issuers to substitute benefits between EHB categories, beginning with plan year 2020, if the State in which the plan will be offered permits such substitution and notifies HHS of its decision to allow substitution between categories. We also add a clarification at § 156.115(b)(3)(i) that plans with substitutions are not relieved of their requirements under § 156.115(a), including the requirement to cover preventive health services, as required under 45 CFR part 147.

We are finalizing 2020 as the first plan year in which issuers, with the permission of the State, may substitute benefits between categories to align with the first year for which States may update their EHB-benchmark plans under § 156.111.

We believe States are best positioned to weigh the benefits of innovative plan design with any effects on State risk pools, and therefore, will only permit substitution between EHB categories in States that have notified HHS that substitution between EHB categories is permitted by the State. Further, because States are generally the primary enforcers of EHB requirements, including the prohibition on discrimination at § 156.125, we believe States can best assure that plan designs meet the needs of their State residents. We anticipate that States will notify HHS of their decision, if any, to allow substitution between EHB categories through the same means States use to notify HHS of an updated EHB-benchmark plan selection under § 156.111. If a State wishes to permit between-category substitution, it will notify HHS, and that notification will be in effect unless and until the State notifies HHS otherwise. States that permit between-category substitution should work with their issuers to ensure they are aware of this option. We plan to post on CCIIO's website a list of States that allow substitution between EHB categories.

Comment: The majority of commenters to this proposal expressed concerns about this proposed policy, and many commenters to this proposal raised concerns about this policy's potential impact on the risk pool. Specifically, commenters were concerned that the proposal would permit issuers to design products that are intended to be unattractive to higher-cost populations to discourage enrollment from these populations. Some of these commenters were concerned about resulting adverse selection, and were concerned that finalizing the policy could ultimately interfere with the stability of the individual and small group market risk pools. Several commenters were concerned that the requirement that substituted benefits be actuarially equivalent does not address this concern, because actuarial equivalence is based on a standard population and cannot take into account the potential effects of adverse selection. Commenters were concerned that this type of ''gaming'' to deter enrollment from members of certain groups could undermine State risk adjustment programs. Additionally, many commenters requested that if we chose to finalize this proposal, we publish additional guidance clarifying how issuers could utilize substitution between EHB categories without violating antidiscrimination

[78] We proposed July 1, 2018, but recognize that July 1, 2018 is a Sunday, so we are finalizing the 2020 deadline as July 2, 2018.

[79] See § 156.115(b)(1)(iii), as established in the EHB Rule.

[80] See Frequently Asked Questions on Essential Health Benefits Bulletin (February 17, 2012), Q9, available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf* and the EHB rule. As finalized in the EHB Rule, issuers of QHPs were permitted to make actuarially equivalent substitutions within statutory categories under § 156.115(b)(1)(ii). Therefore, and as further explained in the EHB FAQ, plans are permitted to impose non-dollar limits, consistent with other guidance, that are at least actuarially equivalent to the annual dollar limits.

requirements. Some commenters stated that they could not conceive of a situation in which cross-category substitution would be useful, and notwithstanding our request for such examples, we did not receive any.[81]

Response: We seek to promote issuer flexibility and consumer choice with this proposal, but recognize that there are potential trade-offs with regard to the risk pool and risk adjustment programs. We believe that States are more attuned to the needs of their issuers and consumers than HHS and can better assess the proper balance between flexibility in plan benefits and risk pool stability. Because issuers are required under the rule to provide benefits that are substantially equal to the EHB-benchmark plan, provide an appropriate balance among the EHB categories such that benefits are not unduly weighted towards any category, and provide benefits for diverse segments of the population, we expect that effects on the risk pool will be limited and can be appropriately managed through State regulation. Because States are generally the primary enforcers of the prohibition on discrimination in the provision of EHB, we defer to States to provide guidance to issuers on how to utilize substitution while meeting anti-discrimination requirements.

Comment: While commenters generally supported efforts to provide States and issuers with additional flexibility, a majority of commenters expressed strong concerns that this specific policy would put undue burden on multiple stakeholders due to increased plan design complexity. For example, many commenters wrote that regulators in States that choose to permit substitution between EHB benefit categories would face additional challenges due to the difficulty of determining whether plans that substituted benefits between EHB offered an adequate distribution of benefits across all EHB categories. One commenter added that evaluating plans that incorporated substitution between EHB categories would be more difficult for States than evaluating plans with substitution within EHB categories, because when comparing the allowed cost associated with particular types of services and limits on those services with other services in the same EHB category, the same dollar amount represents the same proportion of all services in that EHB category. However, this equivalence of dollar amounts and proportionality does not apply when comparing between different categories, making a comparison more difficult. Relatedly, another commenter noted that the lack of uniformity among plans this policy could produce could increase administrative burden on issuers, as well as States, by making it more difficult for issuers to conform plans to filing templates related to QHP certification.

Due to concerns including additional burden on State regulators, commenters also requested that if we were to finalize this proposal, States be permitted to bar substitution between EHB categories.

Almost all commenters asked that we consider the increased burden that consumers would face when comparing plans due to plan complexity related to a possible lack of uniformity across EHB benefit categories and across available plans. In particular, commenters noted that it would become more difficult for consumers in States that chose to permit this option to make meaningful comparisons between plans due to the difficulty in determining whether benefits had been substituted between EHB categories and, if so, whether the resulting coverage package adequately met their needs. One commenter added that these difficulties could also undermine the value of the market signals that consumers' choices currently generate to issuers and other key stakeholders.

Finally, in addition to concerns about consumer burden due to increased plan complexity, many commenters also objected to this proposal due to the possibility that it could undermine coverage for services that are crucial for vulnerable consumers and prevent coverage of chronic conditions.

Response: We agree that permitting substitution between EHB categories could make it more difficult for State regulators to review plans. However, we believe States should have the flexibility to determine whether allowing such a policy will in fact create challenges for State regulators, and if so, whether those challenges are offset by the benefits of allowing more innovation in plan design in the form of between-category substitution. Under the policy we are finalizing, States that determine that allowing substitution between EHB categories would pose excessive burden on regulators have the authority to withhold permission and avoid such burden.

In response to comments, we are finalizing that substitution between categories would only be permitted if the State in which the plan will be offered has notified HHS that substitution between EHB categories is permitted in the State. We recognize that State legislative cycles may make it challenging for States to adopt legislative requirements allowing or prohibiting substitution between categories in time for plan year 2020. By finalizing this notification approach, we seek to make it easier for States to immediately exercise the flexibility provided in this rule.

We appreciate the comment about increased burden on issuers. Because issuers are already familiar with substituting benefits within benefit categories, we do not believe that broadening the policy to allow benefit substitution between benefit categories will create additional burden for issuers. However, if it does, issuers have the discretion to avoid additional burden by choosing not to substitute benefits between EHB categories, even if allowed by their State. If a State chooses, we believe issuers should be permitted to decide whether the additional flexibility in plan design provided by substitution between categories is worth any additional required effort. We also encourage States to consider the impact on issuers as they weigh whether to allow substitution between categories.

We recognize that consumers may face some additional burden in comparing plans when States allow between-benefit substitution and one or more issuers in the State utilize such substitution. However, we believe permitting substitution between categories could offer significant benefit to consumers in the form of more choices, particularly those actively engaged in shopping for health plans. Some consumers are likely to find plans that better meet their needs under this change, because issuers are likely to make substitutions that fulfill consumer demands. Further, we believe States are best positioned to weigh the benefits of innovative plan design with the potential for increased burden for consumers in their individual and small group markets.

We believe that this change will not undermine coverage for vulnerable consumers or prevent coverage of chronic conditions, because issuers will still be required to offer benefits substantially equal to the EHB-benchmark plan, cover each EHB category without undue weight toward any, provide benefits for diverse segments of the population, and refrain from discrimination 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.

[81] One commenter submitted what they described as an example of how an issuer could use this policy to promote the use of high-value services, but their example was a case of adjustments to actuarial value, as opposed to an example of substitution between EHB categories.

d. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the PPACA directs the Secretary of HHS to determine an annual premium adjustment percentage, which is used to set the rate of increase for three parameters detailed in the PPACA: 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;[82] 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 in the annual 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 estimates and projections of average per enrollee employer-sponsored insurance premiums from the NHEA, which are calculated by the CMS Office of the Actuary. Accordingly, using the employer-sponsored insurance data, the premium adjustment percentage for 2019 is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2018 ($6,396) exceeds the most recent NHEA estimate of per enrollee employer-sponsored insurance premiums for 2013 ($5,110).[83] Using this formula, the premium adjustment percentage for 2019 is 1.2516634051 or approximately 25 percent. We are finalizing this index as proposed. Based on the proposed 2019 premium adjustment percentage, we proposed the following cost-sharing parameters for calendar year 2019.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2019

Under § 156.130(a)(2), for the 2019 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 2019, 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 1.2516634051 for 2019 as proposed 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,[84] we proposed that the 2019 maximum annual limitation on cost sharing would be $7,900 for self-only coverage and $15,800 for other than self-only coverage. This represents an approximately 7 percent increase above the 2018 parameters of $7,350 for self-only coverage and $14,700 for other than self-only coverage.

Comment: Several commenters supported the 7 percent increase in the maximum limitation on cost sharing, saying it permits flexible plan design. Many other commenters objected to the 2019 maximum limitation on cost sharing noting it is the highest increase since 2014, saying the HHS methodology no longer works when paired with plan designs that offer less generous EHBs and asked HHS to revisit factors including the premium adjustment percentage used in the methodology.

Commenters noted that while many people with high health needs benefit from a maximum limitation on cost sharing, the percentage increase in 2019 is more than twice the rate of medical inflation and wage growth and far higher than general inflation. Two commenters asked HHS to spread the maximum limitation over the benefit year to reduce the financial burden on chronically ill enrollees whose medical conditions require them to meet the limitation during the first month or quarter of the year.

Response: The annual maximum limitation on cost sharing reflects changes in the underlying economic data, as stated above. We are sympathetic to the hardship faced by those whose health needs require them to meet their maximum limitation on cost sharing early in the year, but the indexing of this parameter is required by statute, and a payment plan for the maximum annual limitation is inconsistent with industry practice. We are finalizing the 2019 maximum limitation on cost sharing as proposed.

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

Sections 1402(a) through (c) of the PPACA direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in 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. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the PPACA, section 1402(c)(1)(B)(ii) of the PPACA 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 PPACA (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. As we discussed above, the 2019 maximum annual limitation on cost sharing is $7,900 for self-only coverage and $15,800 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2019 benefit year and our proposed results.

Consistent with our analysis in the 2014 through 2018 Payment Notices, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to

[82] As noted above, although the individual shared responsibility payment in section 5000A is reduced to $0, effective for months beginning after December 31, 2018, individuals may still have a need to seek certain exemptions under section 5000A of the Code to obtain catastrophic coverage after 2018.

[83] We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. See ''NHE Projections 2016–2025—Tables'' available at *https://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/proj2016.pdf.*

[84] *See http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

the estimated 2019 maximum annual limitation on cost sharing for self-only coverage ($7,900). 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 2019, the test silver level QHPs included a PPO with typical cost-sharing structure ($7,900 annual limitation on cost sharing, $2,350 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing ($5,250 annual limitation on cost sharing, $3,050 deductible, and 20 percent in-network coinsurance rate), and an HMO ($7,900 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, $500 emergency department visit, $25 primary care office visit, and $55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the proposed 2019 AV Calculator and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 100 and 150 percent FPL (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL (⅔ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL (½ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we proposed that the maximum annual limitation on cost sharing for enrollees in the 2017 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately ⅕, rather than ½. 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 ⅔, as specified in the statute, and as shown in Table 10. These proposed reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three model QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level. We are finalizing these reductions as proposed.

In prior years, we have found that for individuals with household incomes of 250 to 400 percent of the FPL, without any change in other forms of cost sharing, any reduction in the maximum annual limitation on cost sharing will cause an increase in AV that exceeds the maximum 70 percent level set in the statute. In the Market Stabilization Rule, we analyzed the effect of reducing the maximum annual limitation on cost sharing based on how we calculated the 2018 reduced maximum annual limitation on cost sharing. We stated that we were not certain what the AV spread of plan designs will be under the finalized policy, whether issuers will in fact reduce the AVs of their base silver plans to the lower end of the *de minimis* range, and whether issuers will retain plan designs above the 70 percent AV range and that we would monitor 2018 standard silver plan designs. As a result, we did not propose to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent FPL.[85]

We note that for 2019, as described in § 156.135(d), States are permitted to submit for approval by HHS State-specific datasets for use as the standard population to calculate AV.[86] No State submitted a dataset by the September 1, 2017 deadline.

TABLE 10—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2019

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2019	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2019
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	$2,600	$5,200
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,600	5,200
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	6,300	12,600

Comment: Several commenters objected to reducing the maximum annual limitation on cost sharing by only one-fifth for enrollees with 200–250 percent FPL, calling the resulting reduced maximum annual limitation on cost sharing about 28 percent of income in this category and too high for most consumers. Commenters asked HHS to revise its test plan, with one commenter saying it does not reflect shifts in plan network type and structure and, as a result, hurts enrollees in this income level.

Response: When developing our test plan, we generally try to match features of actual 2018 plans submitted for certification. We understand State-by-State plans may differ from the HHS test plans and we will continue to apply statutory reductions in maximum annual limitation on cost sharing to plans that most accurately represent those submitted for certification.

[85] 2014 Payment Notice, 78 FR at 15481; Market Stabilization Rule. 82 FR at 18370–18371.

[86] The annual deadline for submitting State specific data for the AV Calculator was announced August 15, 2014. See *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/final-state-avc-guidance.pdf.*

Comment: One commenter cautioned HHS against introducing a new plan variation for enrollees with incomes between 250–400 percent FPL in the absence of Federal payments to issuers for cost-sharing reductions, stating that additional requirements to provide reduced cost sharing would cause issuers to increase premium for all enrollees, and disproportionately hurt those not eligible for any or all subsidies.

Response: We share the commenter's concern that additional reductions for some enrollees could result in higher charges for others without other changes. We will continue to monitor plan AV and benefit design for impact on premiums and out-of-pocket costs.

f. Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

Section 1302(d)(2) of the PPACA directs the Secretary to issue regulations on the calculation of AV and its application to the levels of coverage. In the 2013 EHB Rule, HHS finalized the requirements for the calculation of AV for stand-alone dental plans. Specifically, § 156.150 directs SADPs to cover the pediatric dental EHB at one of two AV levels, within an allowable de minimis variation of +/− 2 percentage points.

We proposed to remove the requirement under § 156.150(b) for SADP issuers to meet the low (70 percent +/− 2 percentage points) or high (85 percent +/− 2 percentage points) AV level. We are finalizing the elimination of the requirement that SADP issuers offer EHBs at the low or high levels of coverage. The PPACA does not specifically require SADP issuers to offer coverage at the high or low levels of AV. Removing the AV level requirement will give SADP issuers the opportunity to offer more flexible plan designs to consumers. In previous comments, SADP issuers had noted that it is difficult to meet the low AV requirement and offer preventive care without cost sharing, to which consumers are accustomed in the large group market. Issuers could offer SADPs at varying premiums and levels of coverage, so long as they continue to offer the pediatric dental EHB and meet the annual limitations on cost sharing. We believe that this will allow consumers to select from a greater variety of plans and find one that is more likely to meet their specific needs.

We are not finalizing the elimination of the requirement that SADP issuers certify their plans' level of coverage of EHB, as proposed. We will no longer require certification of the level of coverage since SADPs will no longer be required to be offered at certain levels of coverage. However, HHS will continue to require certification by a member of the American Academy of Actuaries of the AV of the SADPs' coverage of EHB. HHS will consider ways to use the certified AV to provide consumers with additional information to assist in plan selection.

Comment: Several commenters opposed the proposal. They expressed concern that the removal of AV requirements for EHB would allow SADP issuers to offer plans with little value, and that consumers would have difficulty comparing SADPs. Several commenters requested that HHS establish a minimum AV of 70 percent for EHB covered by SADPs, and that the level of coverage of EHB of an SADP be displayed to consumers when they choose plans.

Several commenters supported the proposal. They expected the proposal to result in greater plan choice for consumers. Some also expected SADPs to have greater ability to maintain similar cost sharing from year to year, since SADP issuers would not be required to alter their plans to meet a particular level of coverage. One commenter observed that AV for pediatric EHB is a poor indicator of plan value for SADPs, since most SADP enrollees are adults. Some commenters requested that HHS implement consumer support tools to aid consumers in choosing among SADPs.

Response: In order to facilitate the implementation of consumer support tools related to SADPs in the future, we are not finalizing the elimination of the requirement that SADPs' AV for EHB be certified by a member of the American Academy of Actuaries. Further, we are codifying an operational requirement that such certification be reported to the Exchange, which issuers of SADPs have already been fulfilling, as part of the QHP certification process.

We believe consumers benefit when they have a range of plan choices, including some plans with lower premiums and a lower AV. All SADPs will continue to be required to cover the pediatric dental EHB and to limit annual cost sharing on EHB. We expect many SADPs with AVs at and above 70 percent will remain available to consumers, even without a minimum AV standard, because SADPs often provide preventive services without cost sharing. While we acknowledge that removing AV standards will make plan comparison more difficult for some consumers, we note that standardized levels of coverage of pediatric dental EHB are not a useful plan comparison tool for the large share of SADP enrollees who are adults. HHS will consider ways to provide consumers with additional information to assist in comparison and selection of SADPs.

Comment: Some commenters questioned whether an SADP with a different AV from one year to the next would be considered the same plan for the purposes of guaranteed renewability or plan crosswalk.

Response: We note that guaranteed renewability requirements at 45 CFR 147.106 generally do not apply to SADPs because they are excepted benefit plans. HHS plans to develop a plan crosswalk hierarchy for Exchanges that use the Federal eligibility and enrollment platform that does not rely on SADPs being offered at either a high or low level of coverage.

3. Qualified Health Plan Minimum Certification Standards

a. Qualified Health Plan Certification (Subpart C)

HHS is committed to recognizing States' role as the primary regulator of their insurance markets, and has made a number of recent changes in the QHP certification process to promote this role, and to limit duplicative oversight over issuers. Previously, in the Guidance to States on Review of Qualified Health Plan Certification Standards in Federally-facilitated Marketplaces for Plan Years 2018 and Later,[87] released on April 13, 2017, we outlined areas where, starting in plan year 2018, HHS began relying on State reviews of QHP certification standards for States with FFEs, including States with FFEs that perform plan management functions in partnership with HHS. We made these changes to streamline the QHP certification process and avoid duplicative Federal and State efforts. In that guidance, we provided that in FFE States that do not perform plan management functions, HHS will continue to review QHP data, but will rely on State review for licensure and good standing standards required at § 156.200(b)(4), and for network adequacy standards required at § 156.230. For FFEs in States performing plan management functions, HHS will continue to rely on State plan data review for QHP certification standards, including for service area and prescription drug formulary outliers and non-discrimination in cost sharing. We stated that we will continue to review plan data relating to Federal funds or plan display on *HealthCare.gov*, such as cost-sharing reductions structures, data

[87] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QHP-Certifcation-Reviews-Guidance-41317.pdf.*

integrity, and plan crosswalks to implement annual re-enrollment at § 155.335(j). In the proposed rule, we reaffirmed this approach, and did not propose changes to this guidance.

To further streamline QHP certification by avoiding duplicative reviews, we also previously announced in the QHP Rate Outlier Analysis for Plan Year 2018 and Beyond [88] that we would rely on States to identify rate outliers for purposes of QHP certification,[89] except for those States that do not have an Effective Rate Review Program. These changes were intended to allow States and issuers greater flexibility in facilitating the certification of plans best suited to their markets, while avoiding duplicative State and Federal activities. We did not propose any changes to the approach described in this guidance.

In the Market Stabilization final rule, HHS also finalized several standards to affirm the traditional role of States in overseeing their health insurance markets while reducing the regulatory burden of participating in Exchanges for issuers for the 2018 plan year.

In the proposed rule, we continued these efforts to enhance States' role in the QHP certification process. We proposed to continue to enhance the State flexibilities in QHP certification that began for plan year 2018 by identifying additional areas where States are already performing reviews that are duplicative of the Federal QHP certification process and incorporating these reviews into the QHP certification process. In addition to empowering States, we believed these proposals would reduce issuer burden.

We proposed to extend for the 2019 benefit year and beyond policies related to QHP certification standards for network adequacy (§ 156.230) and essential community providers (§ 156.235) that we had finalized in the Market Stabilization final rule for only plan year 2018. Specifically, with respect to network adequacy, we proposed to rely on the States' reviews in States in which an FFE is operating, provided the State has a sufficient network adequacy review process. For the 2019 benefit year and beyond, we proposed to defer to the States' reviews in States with the authority to enforce standards that are at least equal to the ''reasonable access standard'' defined in § 156.230 and means to assess issuer network adequacy. In States that do not have the authority and means to conduct sufficient network adequacy reviews, we proposed for the 2019 benefit year and beyond to rely on an issuer's accreditation (commercial, Medicaid, or Exchange) from an HHS-recognized accrediting entity, which we proposed would include the three accrediting entities HHS has previously recognized for the accreditation of QHPs: The National Committee for Quality Assurance, URAC, and Accreditation Association for Ambulatory Health Care.[90] Unaccredited issuers would be required to submit an access plan as part of the QHP application. To show that the QHP's network meets the requirement in § 156.230(a)(2), the access plan would need to demonstrate that an issuer has standards and procedures in place to maintain an adequate network consistent with the National Association of Insurance Commissioners' Health Benefit Plan Network Access and Adequacy Model Act (the Model Act is available at *http://www.naic.org/store/free/MDL-74.pdf*). We proposed to further coordinate with States to monitor network adequacy, for example, through complaint tracking.

With respect to QHP certification review for the essential community provider (ECP) standard, we proposed for the 2019 benefit year and beyond that we would continue to allow issuers to use the ECP write-in process to identify ECPs that are not on the HHS list of available ECPs and would maintain the 20 percent ECP standard. We believe this standard will substantially reduce the regulatory burden on issuers while preserving adequate access to care provided by ECPs. As in previous years, if an issuer's application does not satisfy the ECP standard, the issuer would be required to include as part of its application for QHP certification a satisfactory narrative justification describing how the issuer's provider networks, as presently constituted, provide an adequate level of service for low-income and medically underserved individuals and how the issuer plans to increase ECP participation in the issuer's provider networks in future years. At a minimum, such narrative justification would include the number of contracts offered to ECPs for the applicable plan year; the number of additional contracts an issuer expects to offer and the timeframe of those planned negotiations; the names of the specific ECPs to which the issuer has offered contracts that are still pending; and contingency plans for how the issuer's provider network, as currently designed, will provide adequate care to enrollees who might otherwise be cared for by relevant ECP types that are missing from the issuer's provider network.

We are finalizing as proposed the policies for network adequacy (§ 156.230) and ECPs (§ 156.235).

Comment: Many commenters supported the network adequacy proposal, favoring the elimination of duplicative reviews, while others opposed the proposal, stating that States' and accrediting entities' review processes do not do enough to ensure enrollees have adequate access to necessary care. We also received many comments that strongly opposed the continuation of the 20 percent ECP standard and urged that HHS return to the 30 percent ECP standard, expressing concerns that the lower threshold requirement will result in access barriers to care for low-income consumers.

Response: We are finalizing as proposed our policies for network adequacy and ECP, as we believe they will continue to help stabilize the markets by reducing regulatory burden on issuers, while also preserving adequate access to care, and streamlining the QHP certification process. We have relied on State and accrediting entities for this review in the past, and believe they provide appropriate review because both typically have requirements in place that specifically address access to adequate networks. Many States already address issuer network adequacy in State-specific regulation. The National Committee for Quality Assurance requires accredited plans to create standards for the number and geographic distribution of providers and establish standards regarding the ability of consumers to access care. Similarly, URAC requires that plans have proper methods in place to build, manage, and evaluate their networks. We will also continue to monitor enrollee complaints for access concerns.

For plan years 2019 and later, HHS proposed to further expand the role of States in the QHP certification process for FFEs, including FFEs where the State performs plan management functions. Specifically, we proposed to defer to States for additional review

[88] *https://www.regtap.info/uploads/library/QHP_RateOutlier_FAQ_5CR_071017.pdf.*

[89] This review generally identifies rates that are relatively low compared to other QHP rates in the same rating area. The identification of a QHP rate as an outlier does not necessarily indicate inappropriate rate development; instead, this information helps inform the determination of whether certifying the QHP to be offered on the Exchange would be in the interest of consumers.

[90] Recognition of Entities for the Accreditation of Qualified Health Plans 77 FR 70163 (November 23, 2012) and Approval of an Application by the Accreditation Association for Ambulatory Health Care (AAAHC) To Be a Recognized Accrediting Entity for the Accreditation of Qualified Health Plans 78 FR 77470 (December 23, 2013).

areas, including accreditation requirements at § 156.275, compliance reviews at § 156.715, minimum geographic area of the plan's service area at § 155.1055, and quality improvement strategy reporting at § 156.1130, if feasible and appropriate. In the proposed rule, we stated that we believed States currently perform reviews in these areas that are duplicative of the Federal reviews for QHP certification. As a result, we did not believe this policy would require States to undertake additional reviews or change existing reviews to match the Federal standards for QHPs. We are not finalizing the proposal to defer to States for reviews in these four areas.

Comment: Some commenters supported the proposal to defer the additional review areas of accreditation, minimum geographic area of the plan's service area, compliance reviews, and quality improvement strategy reporting to States for purpose of QHP certification, while some commenters—including some States—opposed the proposal, citing lack of State resources, insufficient staff, and the possibility of increased costs.

Response: We are not finalizing as proposed the deferral to States for the review of service area; accreditation; compliance review—which in this context we interpreted to be review of an issuer's organizational chart and compliance plan; and quality improvement strategy reporting. Based on comments received, we understand that States presently lack resources, including staffing resources, to conduct these reviews. We are less concerned about the potential for Federal reviews to impose unnecessary additional burden on issuers, given information from States and commenters that not all States currently perform these reviews. Our proposal was intended to eliminate duplication in reviews, not to compel States to take on reviews that they are not already performing.

b. QHP Issuer Participation Standards

Section 156.200 sets forth many of the standards a plan must meet to be certified as a QHP. We proposed to amend paragraph (b)(2) to add a cross reference to proposed § 155.706 to align with other changes made throughout this final rule regarding changes to SHOP. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule. We are finalizing the change as proposed.

c. Additional Standards Specific to SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 156.285)

As discussed in the following section, we proposed and are finalizing a modification to the regulatory requirements regarding additional standards specific to SHOP for plan years beginning on or after January 1, 2018 and are introducing those requirements in a new § 156.286. To reflect the proposal that the requirements currently in § 156.285 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 156.285 and add paragraph (f), to state that the section would only apply for plan years that begin prior to January 1, 2018. We discuss the new standards applicable for plan years beginning on or after January 1, 2018 in the following section. These changes will be effective on the effective date of the final rule.

Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule; we are finalizing these policies as proposed.

d. Additional Standards Specific to SHOP for Plan Years Beginning on or After January 1, 2018 (§ 156.286)

As discussed above, we proposed to make § 156.285, which describes the requirements on QHP issuers participating in SHOPs to accept enrollment and payment information from a SHOP on behalf of an employer or enrollee applicable only for plan years beginning prior to January 1, 2018, and to modify the additional standards specific to QHP issuers participating in SHOPs applicable for plan years beginning on or after January 1, 2018, through the introduction of a new § 156.286. We proposed that new § 156.286 would include only those standards that have been applicable under § 156.285 that would continue to apply to the SHOPs under the proposed approach discussed earlier in this preamble, with minor modifications and clarifications.

We proposed to retain § 156.285(a) as § 156.286(a). However, we proposed to require issuers to accept payment not only from the SHOP, but from a qualified employer or enrollee or a SHOP, to reflect the proposal that a SHOP would not be required to process enrollments and payments. We also proposed not to include the requirement currently in § 156.285(a)(4)(ii), which prohibits issuers in FF–SHOPs from using average enrollee premiums, as the FF–SHOPs and SBE–FPs for SHOP, would no longer be involved in premium payments. For the same reason, we also proposed a narrower version of § 156.285(b) as § 156.286(b), requiring only that issuers adhere to the enrollment periods and processes established by the SHOP consistent with § 155.726, and establish uniform enrollment timelines and processes for qualified employers and group members. We also proposed in § 156.286(c) to include only those requirements from § 156.285(c) that do not relate to the payment and enrollment processes that we have proposed would no longer be required.

We proposed not to include a paragraph mirroring paragraph (d) of § 156.285. This reflects our proposal to remove the requirements contained in current § 155.735, and generally not to impose coverage related timelines on issuers of QHPs through the SHOPs for plans beginning on or after January 1, 2018. We proposed to include a paragraph mirroring § 155.285(e) as § 156.286(d).

Finally, under our proposed and finalized approach, SHOPs will no longer be required to provide employee enrollment functionality. When enrollments are completed by working with SHOP issuers or SHOP-registered agents or brokers, which will be the case for FF–SHOPs, it may not always be immediately apparent to the issuer whether the enrollment is through the SHOP, and whether it is part of an employer's offering a choice of plans. To ensure that issuers offering QHPs through a SHOP do so in a manner that is consistent with our new interpretation of the SHOP provisions of the statute, we proposed to add new paragraphs (e) and (f) in § 156.286. These will require that QHP issuers offering a QHP through the SHOP accept enrollments from groups in accordance with the employer choice policies applicable to the SHOP under § 155.706(b)(3), that they maintain processes sufficient to identify whether a group market enrollment is an enrollment through the SHOP, and they maintain records of SHOP enrollments for a period of 10 years following the enrollment. Proposed paragraph (f) also would require issuers to utilize a uniform enrollment form, as required by section 1311(c)(1)(F) of the PPACA. As noted in the preamble to § 155.716, we intend to update the single employer application to reflect our changes in § 155.731. An issuer will be considered to satisfy this requirement if it uses that application form.

Finally, we proposed in paragraph (g) to state that the requirements contained within § 156.286 are only applicable for

plan years beginning on or after January 1, 2018.

We are finalizing these policies as proposed, with a minor change to § 156.286(a)(1) to reflect that SBEs can continue operating their SHOPs under current practices. These changes are effective as of the effective date of this rule.

Comment: We received a comment that requested clarification on the issuer requirements at § 156.286(a)(1), regarding whether the proposal precluded State Exchanges from directing issuers offering QHPs in their SHOPs to accept payments only from the SHOP.

Response: State Exchanges that do not take advantage of the flexibilities described above for their SHOPs are encouraged to continue operating in a manner consistent with § 156.285, or in a way that best meets the needs of their small group market. The requirements in § 156.286(a)(1) represent minimum SHOP requirements for issuers that would apply to all SHOPs, including those that take advantage of the flexibilities provided for by this final rule, like the FF–SHOPs. We did not intend that the leaner approach to SHOP prohibit State Exchanges from requiring QHP issuers in their SHOPs from accepting payments on behalf of a qualified employer or enrollee from sources other than the SHOP, as the FF–SHOPs had previously done. We have clarified the regulatory text accordingly.

e. Meaningful Difference Standard for Qualified Health Plans in the Federally-Facilitated Exchanges (§ 156.298)

We proposed to remove § 156.298 to eliminate meaningful difference standards for QHPs offered through an FFE or SBE–FP. Under this standard, in order to be certified as a QHP, a plan must be meaningfully different from all other QHPs offered by the same issuer of that plan within a service area and level of coverage in the Exchange. As defined in § 156.298(b), QHPs are considered meaningfully different from other plans if a reasonable consumer would be able to identify one or more material differences among five key characteristics between the plan and other plans to be offered by the same issuer.

This meaningful difference standard was implemented to make it easier for consumers to understand differences between plans, and choose the right plan option for them. However, with fewer issuers participating in the Exchange, and fewer plans for consumers to choose from, we proposed to remove these standards, as we no longer believe the requirement is necessary. We believe removing the meaningful difference standard would encourage plan design innovation, by providing more flexibility to issuers in designing plans, and thus increase plan offerings and choice for consumers.

We are finalizing this policy as proposed.

Comment: While some commenters supported removing the meaningful difference standard, several commenters opposed removing it, stating that the standard helps consumers avoid confusion and improves the consumer shopping experience. Some commenters stated that removing the standard would decrease the comparative value of the data and increase the probability of duplicative QHP offerings, with one commenter stating that removing the standard would encourage a proliferation of plans. One commenter stated that removing the standard could lead to benefit designs aimed to attract healthy enrollees and repel sick enrollees. One commenter recommended that we provide an exception to the meaningful difference standard in cases where a comparison is not feasible, while maintaining the requirement in cases where comparisons are feasible. One commenter supported removing the standard as long as certain conditions outside the scope of this rule were met.

Response: We believe that removing the meaningful difference standard will not substantially increase the number of materially similar plans from the same issuer. Plan selection tools provide consumers with information to distinguish between plans and see similarities or differences. With fewer plans on the Exchanges than in prior years, we believe removing this standard will encourage innovation and increase plan offerings and choice for consumers, the benefits of which would outweigh any potential confusion.

f. Other Considerations

We sought comment on ways in which HHS can foster market-driven programs that can improve the management and costs of care and that provide consumers with quality, person-centered coverage. As we stated in the 2017 and 2018 Payment Notices, we 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. We sought comment on ways in which we can facilitate such innovation, and in particular on whether there are regulations or policies in place that we should modify in order to better meet the goals of affordability, quality, and access to care.

We also sought comment on how we may encourage value-based insurance design within the individual and small group markets and ways to support issuers in using cost sharing to incentivize more cost-effective enrollee behavior and higher quality health outcomes, in accordance with section 2713(c) of the PHS Act. Currently, under our rules, issuers have considerable discretion in the design of cost-sharing structures, subject to certain statutory AV requirements, non-discrimination laws and rules,[91] and other applicable law, such as MHPAEA.

We would like to encourage issuers to offer HDHPs that can be paired with a health savings account (HSA) as a cost effective option for enrollees. While the proportion of available HSA-eligible HDHPs has been stable in the FFEs, the percentage of enrollees in HDHPs has decreased slightly over the last 3 years as there are certain technical barriers for issuers in offering HDHPs.[92] We are particularly interested in exploring how to use plan display options on *HealthCare.gov* to promote the availability of HDHPs to applicants, and sought comment on how best to do so.

We are also interested in value-based insurance designs that focus on cost effective drug tiering structures; address overused, higher cost health services; provide innovative network design that incentivizes enrollees to use higher quality care; and promote use of preventive care and wellness services. We solicited comments on how HHS can better encourage these types of plan designs, and whether any existing regulatory provisions or practices discourage such designs.

Comment: Many commenters supported HHS exploring ways to encourage innovation and value-based insurance design. There was general support for HHS to drive towards improved health outcomes and efficient health care delivery. Commenters noted that issuers should be encouraged to

[91] We note that issuers are also subject to Federal civil rights laws, including Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

[92] For instance, the maximum annual limitation on cost sharing established at section 1302(c) of the PPACA is increasing at a faster rate than the maximum out of pocket cost limits for HDHPs under section 223 of the Code. Therefore, a plan that utilizes the maximum annual limitation on cost sharing under the PPACA would not meet the requirements to be an HDHP under the Code that could be paired with an HSA.

engage in value-based insurance design that utilizes clinical effectiveness research and drives consumers to efficient high quality providers. Commenters questioned how services would be deemed high-value and cautioned against disincentivizing consumers from seeking preventive and wellness care, and care for chronic conditions. Commenters suggested that HHS seek public comment on services that are high value or leverage data from comparative effectiveness research to identify low-value services.

Commenters generally supported increasing transparency of health information, but cautioned that consumers would need education and tools in order to make information useful. Some requested that additional information be incorporated into *HealthCare.gov*, plan selection tools, the Summary of Benefits and Coverage, or the out-of-pocket estimator tool.

Others suggested that specific alternative payment options be allowable, such as reference pricing or allowing issuers the flexibility to apply the annual limitation on cost sharing to accumulate differently in tiered networks.

Comments were mixed regarding HSA-eligible HDHPs. Many commenters cautioned that HDHPs do not meet the needs of low-income consumers and urged that HHS provide appropriate explanations and ensure there are consumer protections to make sure consumers make appropriate plan selections. Others noted that *HealthCare.gov* should provide more information on how to use HDHPs and how to set up HSAs. Others commented that promoting HDHPs would require training of Navigators and call center staff to handle additional questions. Some noted that *HealthCare.gov* support should not answer questions more appropriate for HSA custodians.

Commenters noted the statutory and regulatory issues with offering HSA-eligible HDHPs on Exchanges, including the misalignment of annual limitations on cost sharing between the PPACA and the Code. Others requested that the IRS expand preventive care safe harbors under section 223(c)(2)(C) of the Code to include services and benefits related to the management of chronic conditions and medications.

One commenter suggested that HHS provide subsidies in the form of HSA contributions instead of cost-sharing reductions. Other commenters offered additional responses related to drug pricing, encouraging HHS to prioritize the transparency of drug pricing in general, and other health care costs. Others noted that with the removal of standardized options, HHS should consider other ways to incentivize issuers to offer at least some QHPs with prescription drugs not subject to the deductible. Other commenters noted specific examples where issuers were waiving cost sharing for high value prescription drugs, such as those to treat high blood pressure. Others suggested that drug rebates could be available to consumers at the point of sale. Additional commenters expressed concerns about changes to the 340B drug discount program.

Response: We appreciate these comments and will take them under consideration. We note that the Treasury Department and the IRS have jurisdiction over HSAs and HSA-eligible HDHPs under section 223 of the Code.

4. Standards for Downstream and Delegated Entities (§ 156.340)

Section 156.340 sets forth the responsibilities of a QHP issuer and its applicable downstream entities. We proposed to amend paragraph (a)(2) to add a cross reference to proposed § 155.706 to align with other changes made throughout this rule regarding SHOP. Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule.

We are finalizing the change as proposed.

5. Eligibility and Enrollment Standards for Qualified Health Plan Issuers on State-Based Exchanges on the Federal Platform (§ 156.350)

Section 156.350 describes the eligibility and enrollment standards for issuers that offer QHP coverage in the SBE–FPs. Currently, § 156.350(a)(1) and (2) state that for a QHP issuer to participate in an SBE–FP for SHOP, it must comply with the requirements at § 156.285(a)(4)(ii) and § 156.285(c)(5) and (c)(8)(iii), respectively. However, as discussed elsewhere in this final rule, to align with our proposal regarding the SHOPs, we proposed, and are finalizing, that these referenced requirements at § 156.285 would not be applicable for plan years beginning on or after January 1, 2018, effective on the effective date of this rule. Therefore, we proposed to amend § 156.350(a)(1) and (a)(2) to specify that they only apply through plan years beginning prior to January 1, 2018.

Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule. We are finalizing the changes as proposed.

6. Minimum Essential Coverage

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

A CHIP program is a type of government-sponsored coverage, defined under title XXI of the Act that provides low-cost health coverage to children in low-income families that do not otherwise have health coverage. States may be eligible to receive Federal funds to initiate and expand such programs. A CHIP buy-in program, a ''full pay'' option where a covered family pays the full premium typically without any Federal or State assistance, often provides similar or identical benefits as the State's CHIP program under title XXI of the Act (the title XXI CHIP program) for children in families that do not financially qualify for the title XXI CHIP program.[93] We proposed to amend § 156.602 to specifically designate as MEC CHIP buy-in programs that provide identical coverage to that title XXI CHIP program pursuant to the Secretary's authority under section 5000A(f)(1)(E) of the Code. We sought comment on whether CHIP buy-in programs that provide greater coverage than the title XXI CHIP program should be categorically designated as MEC. Finally, we sought comment on whether other types of government-sponsored buy-in programs, such as Medicaid buy-in programs, should be categorically designated as MEC. We are not finalizing the policy to categorically designate as MEC CHIP buy-in programs that provide identical or greater coverage to the title XXI CHIP program.

Comment: Some commenters supported categorically designating as MEC CHIP buy-in programs that provide identical or greater coverage to the title XXI CHIP program because the categorical designation would drive down premiums and out-of-pocket costs for full-pay families, as well as eliminate deductibles. In addition, the change would permit consumers to move between the title XXI CHIP program and CHIP buy-in programs without experiencing a change in benefits. Other commenters expressed concern that a categorical designation would prevent HHS from verifying that the benefits of a CHIP buy-in program are identical to the title XXI CHIP program which could lead to adverse selection in the individual market or erosion of CHIP benefits.

[93] Under IRS Notice 2015–37, individuals who may enroll in a CHIP buy-in program designated as MEC are eligible for MEC under the CHIP buy-in program for purposes of the premium tax credit under section 36B of the Code only if they are enrolled in the program.

Response: Following the publication of the proposed rule, Congress designated qualified CHIP look-alike plans as MEC. Section 5000A(f)(1)(A)(iii) of the Code, as amended by section 3002(g)(2)(A) of the HEALTHY KIDS Act, specifically designates CHIP look-alike plans as MEC. Section 2107 of the Social Security Act, as amended by section 3002(g)(1) of the HEALTHY KIDS Act, defines a CHIP look-alike plan as a CHIP buy-in program that provides ''benefits that are at least identical to the benefits provided'' by the title XXI CHIP program.[94] Therefore, we are not finalizing the proposed changes to § 156.602 since CHIP look-alike plans are now statutorily designated as MEC.

However, because the amendment does not designate all CHIP buy-in programs as MEC, we recognize that States and enrollees may have questions regarding whether a particular State's CHIP buy-in program is MEC. To provide States and enrollees with certainty as to whether their coverage constitutes MEC, States will have the option to verify with HHS that their CHIP buy-in program meets the definition of a CHIP look-alike plan. A State may verify that a CHIP buy-in program is a qualified CHIP look-alike plan by submitting documentation to HHS via the Health Insurance Oversight System (HIOS) (as described in section V of the October 31, 2013 Insurance Bulletin[95]) that provides a detailed summary of the coverage provided by the CHIP buy-in program and the title XXI CHIP program. Upon review and comparison of the coverage, if HHS determines that the CHIP buy-in program provides at least the same coverage as the title XXI CHIP program, then HHS will confirm that the CHIP buy-in program is a CHIP look-alike plan. If HHS determines that the CHIP buy-in program does not provide at least the same coverage as the title XXI CHIP program, then the plan sponsor may work with HHS to modify the CHIP buy-in program to offer at least the same coverage as the title XXI CHIP program. In the alternative, the plan sponsor may apply for MEC recognition through the process outlined in § 156.604 under which HHS will evaluate whether the CHIP buy-in program complies with ''substantially all'' of the provisions of title I of the PPACA that apply to non-grandfathered individual health insurance coverage.

CHIP buy-in plans that are not CHIP look-alike plans may also continue to receive MEC recognition through the MEC application process if the State can demonstrate that the coverage meets substantially all the requirements of title I of the PPACA pertaining to non-grandfathered, individual health insurance coverage.

Comment: One commenter stated that States should have the flexibility to offer a Medicaid buy-in program in an effort to stabilize the market and increase competition.

Response: While we are not finalizing that Medicaid buy-in programs are designated as MEC, HHS invites all States to apply for their Medicaid buy-in programs to be recognized as MEC in the process outlined in § 156.604.

b. Requirements for Recognition as Minimum Essential Coverage for Types of Coverage Not Otherwise Designated Minimum Essential Coverage in the Statute or This Subpart (§ 156.604)

Under § 156.604, the Secretary may recognize coverage as MEC provided HHS determines that the plan meets substantially all the requirements of title I of the PPACA pertaining to non-grandfathered, individual health insurance coverage (the ''substantially all'' standard). In the proposed rule, we sought comment on whether HHS should create a new standard of review under which CHIP buy-in programs must ''substantially resemble'' the title XXI CHIP program under title XXI to qualify as MEC under § 156.604. We are not finalizing a substantially resemble standard of review.

Comment: One commenter stated that the ''substantially resemble'' standard is more meaningful to State CHIP administrators than the ''substantially all'' standard and would allow for more reasonable evaluation by HHS of each individual buy-in program. Some commenters stated the ''substantially resemble'' standard must be better defined and delineated to provide clear guidelines on what constitutes a qualifying buy-in program. The commenters stated that, without clarity, there would be confusion and States could be more arbitrary in their decision-making for the scope of benefits. Other commenters stated that the CHIP buy-in programs should be subject to the ''substantially all'' standard that applies to other MEC applicants. To provide a lesser standard to CHIP buy-in programs could result in fewer benefits for the children in those programs.

Response: After reviewing these comments, we agree that it is important for HHS to provide clear standards of review for the MEC application process and to ensure that enrollees in these programs obtain benefits that are similar to the benefits in PPACA compliant coverage. We are not finalizing a ''substantially resemble'' standard. As described in the previous section, section 5000A(f)(1)(A)(iii) of the Code, as amended by section 3002(g)(2)(A) of the HEALTHY KIDS Act, specifically designates CHIP buy-in programs that provide benefits that are at least identical to the benefits provided by the title XXI CHIP program as MEC. CHIP buy-in programs that do not provide identical or greater benefits than what is provided in the State's title XXI program will be subject to the ''substantially all'' standard for MEC recognition.

7. Quality Rating System (§ 156.1120)

We recognize that social risk factors play a major role in health, and one of our core objectives is to improve patients' outcomes including reducing health disparities. In addition, we seek to ensure that the quality of care furnished by providers and health plans is assessed as fairly and accurately as possible under HHS quality reporting programs, including the Quality Rating System established under section 1311(c)(3) of the PPACA, while helping to ensure that individuals and populations receive high quality, person-centered care. In response to several comments we received from the Request for Information, we continue to assess ways to reduce burden and promote State flexibility in the implementation of all statutorily required Exchange quality programs, including the Quality Rating System, and we continue to prioritize strategies to improve the value for consumers. We received many comments as part of the annual Quality Rating System Call Letter process in response to our request for public comment on whether we should account for social risk factors in the Quality Rating System, which provides quality ratings (or star ratings from 1 to 5 stars) that account for member experience, medical care and health plan administration for QHPs, offered through an Exchange. We did not propose amendments to the Quality Rating System regulations in the proposed rule.

We sought comment as part of this rulemaking on types of social risk factors that may be most appropriate, as well as the methods to account for social risk factors for QHP issuer quality

[94] Extension of Continuing Appropriations Act, 2018; HEALTHY KIDS Act; Federal Register Printing Savings Act of 2017, Public Law 115–120, 101 (2018).

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

reporting. Examples of social risk factors include: Low income subsidy; race and ethnicity; and geographic area of residence. Approaches to account for social risk factors include stratifying measure scores or risk adjustment of a particular measure. We sought comment on which social risk factors could be used alone or in combination, current data sources where this information would be available, and whether other data should be collected to better capture the effects of social risk.

Comment: Although many commenters expressed that accounting for social risk factors in measuring performance is contentious and challenging, there was overall support for the need to address socioeconomic factors that can affect quality in reporting of quality data and for CMS to closely monitor the ongoing work of the Office of the Assistant Secretary for Planning and Evaluation and the National Quality Forum regarding socioeconomic status in health outcomes and quality. Commenters encouraged HHS to increase opportunities for collaboration across all HHS quality rating programs, including the Exchange Quality Rating System, Medicare Advantage and Medicaid health plans and provided some recommendations on methods of accounting for social risk factors in the Quality Rating System. Some commenters did not support adjusting for socioeconomic status because they believe that could be counter-productive and potentially signal an expectation, even acceptance, of lower outcomes for financially disadvantaged consumers.

Commenters provided examples of types of social risk factors and combination of factors that would most appropriately account for QHP issuer quality reporting and clarified which data is readily collected by Exchanges. The types of social risk factors mentioned included patient level data about race and ethnicity; income level; preferred language; disability status; sexual orientation and gender identity; psychological and behavioral status; alcohol and tobacco use; residential address; low-income subsidy eligibility status; and per the recommendations of the National Academies of Sciences, Engineering, and Medicine: Health and Medicine Division,[96] the systematic collection of data in the following domains: Depression, education, financial resource strain, intimate partner violence, physical activity, social connections and social isolation, stress, housing status, insurance status, employment, transportation, incarceration and refugee status. Commenters also provided support for stratifying measure data and not risk adjusting the Quality Rating System for social risk factors, to help plans identify and distinguish efforts to improve quality from efforts to reduce disparities. Commenters stated that stratifying measure results by socioeconomic status of patients within affected measures would highlight disparities, showing plans which subpopulations among their enrollees most need targeted quality improvement efforts.

Response: We appreciate the comments, and will take them under consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the Quality Rating System. We will continue to collaborate with the Office of the Assistant Secretary for Planning and Evaluation, the National Quality Forum, and with issuer, provider, and enrollee stakeholders to assess methods for the collection and application of social risk factor information for future years of the Quality Rating System program.

8. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

We proposed to amend paragraph (b)(2) of § 156.1230 to conform with the proposed amendments to § 155.221. The change requires that, prior to a QHP issuer's internet website being used to complete a QHP selection, the QHP issuer must engage a third-party entity in accordance with § 155.221 to demonstrate operational readiness and compliance with applicable requirements. For a discussion of the provisions of this final rule related to third-party entities performing operational readiness reviews, please see the preamble to § 155.221. We are finalizing the amendments to § 156.1230 as proposed.

Comment: One commenter requested clarification on whether the proposed § 156.1230(b)(2) is meant to apply only when an Exchange delegates the enrollment function to plans operating in the individual market.

Response: No FFE has delegated the enrollment function to plans operating in the individual market. Notwithstanding this, § 156.1230(b) permits QHPs in FFEs to directly enroll individual market applicants in a manner that is considered through the Exchange, to the extent permitted by applicable State law. Paragraph (b)(2) applies in all circumstances where an issuer participating in an FFE performs such a direct enrollment. A QHP issuer participating in an SBE–FP may also, under § 156.350, directly enroll applicants, and must comply with the requirements in § 156.1230(b)(2) as if it were an issuer of QHPs on an FFE when using the direct enrollment pathway.

F. Part 157—Employer Interactions With Exchanges and SHOP Participation

1. Qualified Employer Participation Process in a SHOP for Plan Years Beginning Prior to January 1, 2018 (§ 157.205)

As discussed in the following section, we proposed to modify the regulatory requirements regarding the qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018 and to introduce those requirements in a new § 157.206. To reflect the proposal that the requirements currently in § 157.205 would apply only for plan years beginning before January 1, 2018, we proposed to amend the heading of § 157.205 and add paragraph (h), to state that the section would apply only for plan years that begin prior to January 1, 2018.

Comments related to the proposed approach for SHOP are discussed at the beginning of section III.D.9 of this rule. We are finalizing these policies as proposed. These changes will be effective on the effective date of this rule.

2. Qualified Employer Participation Process in a SHOP for Plan Years Beginning on or After January 1, 2018 (§ 157.206)

Section 157.205 describes requirements for participating SHOP employers. To reflect the proposal to allow SHOPs to operate in a leaner fashion, we proposed several changes to the requirements related to qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018, and proposed to introduce these requirements in § 157.206. With the exception of the proposed changes to the process described here, the process will remain the same as in § 157.205. The proposals described in this section will be effective on the effective date of the final rule.

Paragraph (d) of § 157.205 requires a qualified employer to submit any contribution towards the premiums of any qualified employee according to the standards and processes described in § 155.705. Because we proposed that the requirements in § 155.705 regarding

[96] IOM (Institute of Medicine). 2014. Capturing social and behavioral domains and measures in electronic health records: Phase 2. Washington, DC: The National Academies Press. *https://www.nap.edu/read/18951/chapter/1.*

employer contribution methods will not apply for plan years beginning on or after January 1, 2018, we also proposed that the requirement in § 157.705(d) will not apply for those plan years.

Paragraph (e)(1) of § 157.205 describes obligations of qualified employers to employees hired outside of the initial or annual open enrollment periods. We proposed in § 157.206(d) that qualified employers must provide employees hired outside of the initial or annual open enrollment period with information about the enrollment process. We proposed that the requirement in paragraph (e)(1) of § 157.705, which requires qualified employers to provide these employees with an enrollment period in accordance with § 155.725(g), would not be included in § 157.206, as the requirement in § 155.725(g) will not be applicable for plan years beginning on or after January 1, 2018. We also proposed that the requirement in § 157.205(e)(2) to provide information about the enrollment process in accordance with § 155.725 would not apply for plan years beginning on or after January 1, 2018 to reflect that the process provided for in many of the provisions in § 155.725 will not apply for those plan years.

We also proposed that the requirements in § 157.205(f) regarding the process for notifying the SHOP in the event the eligibility status of an employee, or employee's dependent has changed would not apply for plan years beginning on or after January 1, 2018. Under the approach finalized in this rule for plan years beginning on or after January 1, 2018, SHOPs will not be required to process employee enrollment, so there will be no reason for all qualified employers to provide such information.

Further, we proposed that the requirement in § 157.205(g) that qualified employers adhere to the annual employer election period under § 155.725(c) would not apply for plan years beginning on or after January 1, 2018. Elsewhere, we finalized that the annual employer election period provision in § 155.725(c) will not apply for those plan years, and this change reflects that removal.

Finally, we proposed in paragraph (e) of § 157.206 to include new requirements for qualified employers reflective of the proposed approach for SHOPs generally. First, since we proposed in § 155.716(f) that an employer's determination of eligibility to participate in the SHOP remains valid until the employer makes a change that could end its eligibility under § 155.710(b), we proposed in § 157.205(e)(1) that employers must submit a new application to the SHOP if the employer makes a change that could end its eligibility under § 155.710 or withdraw from participation in the SHOP. Second, because under the changes we have finalized elsewhere in this rule, SHOPs will not be required to process group enrollments, and therefore will not necessarily communicate with QHP issuers about employer eligibility determinations, we proposed to require employers to notify the QHP issuer of an unfavorable eligibility determination. However, we proposed that the employer be required to provide the notification within 5 business days of the end of any applicable appeal process under § 155.741. Specifically, the end of the appeal process could occur when the time to file an appeal lapses without an appeal being filed, when the appeal is rejected or dismissed, or when the appeal process concludes with an adjudication by the appeals entity, as applicable. We also proposed in paragraph (e)(3) to describe the employer's obligations regarding loss of eligibility to participate in a SHOP or termination of enrollment or coverage through the SHOP. Given that under the approach finalized in this rule there will not necessarily be communication between the SHOP and a participating QHP issuer regarding employer eligibility, enrollment, or terminations, there may be no way for the SHOP to notify an issuer in the event an employer becomes ineligible to participate in SHOP. Therefore, we proposed to add paragraph (e)(3) to require employers to notify an issuer of a loss of eligibility to participate in SHOP, or a desire to terminate SHOP enrollment or coverage.

We proposed in paragraph (f) of § 157.205 that the section would apply for plan years beginning on or after January 1, 2018, only.

Substantive comments relating to our proposals regarding SHOP are addressed in section III.D.9 of this rule, as well as in the preamble discussing §§ 156.285 and 156.286. We are finalizing new § 157.206 as proposed, with minor changes to paragraphs (e)(2) and (e)(3). As noted in the preamble to the SHOP sections in part 155, State Exchanges are encouraged to continue to operate their SHOPs as they do today, or design a SHOP within the bounds of the flexibilities being finalized within this rule. To ensure that SHOPs can continue to operate as they do today, we are providing flexibility to employers to allow them not to notify issuers of determinations of ineligibility to participate in the SHOP or their desire to terminate their participation in the SHOP in cases where the SHOP has notified the issuer. We are making this change to recognize that State-based SHOPs may continue to provide these notifications, in which case employers should not be required to provide duplicative notifications. Section 156.206 will become effective as of the effective date of the final rule.

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

1. Reporting of Federal and State Taxes (§ 158.162)

Section 2718 of the PHS Act requires that Federal and State taxes be reported, but that such amounts be excluded from premium revenue when calculating an issuer's MLR and accompanying rebates. However, the statute does not define what is included in Federal and State taxes. The MLR December 1, 2010, interim final rule (75 FR 74864) interprets this language and broadly describes Federal and State taxes that must be reported but are excluded from premiums in the MLR and rebate calculations, and Federal and State taxes that must be reported and are not excluded from premiums in MLR and rebate calculations. In order to provide consistency and clarity for MLR reporting, HHS amended § 158.162 in the 2016 Payment Notice (80 FR 10750) to specify that all issuers must include employment taxes in earned premiums and must not deduct such taxes in the MLR and rebate calculations starting with the 2016 MLR reporting year.

However, we received several comments in favor of allowing issuers to deduct such taxes from these calculations in response to the Request for Information. Therefore, in the proposed rule, we invited comments on whether, in order to encourage issuer participation and competition in the markets, HHS should revise paragraph (a)(2) and paragraph (b)(2)(iv) of § 158.162 to allow all issuers to deduct Federal and State employment taxes from premiums in their MLR and rebate calculations, starting with the 2017 MLR reporting year for reports to be filed by July 31, 2018.

We solicited comments on this approach from all stakeholders, including on whether we should instead amend the MLR regulations to collect the employment tax data separately from other tax data as an informational item on the MLR Annual Reporting Form to gather data to inform a decision regarding whether to amend the regulation for future years, and whether changing the treatment of employment

taxes would be likely to help improve market stability and competition.

Comment: We received almost an equal number of comments opposing and supporting exclusion of Federal and State employment taxes from earned premium in the MLR and rebate calculations. Some who commented in opposition noted that modifying the treatment of employment taxes would contradict HHS's previous decision. Other commenters expressed concern that such policy would raise MLRs without producing greater value for consumers and would undermine consumer protections. Several commenters stated that it is the uncertainty and the changes to the MLR reporting parameters, rather than employment taxes that negatively affect market stability. In contrast, several other commenters stated that excluding employment taxes would improve market stability and provide incentives for issuers to enter or remain in the market. Some commenters stated that the PPACA provides for the exclusion of taxes from the MLR calculation and that including employment taxes is inconsistent with the treatment of other taxes. Lastly, a number of commenters recommended that HHS gather additional information on the impact of excluding employment taxes on consumers and issuers before making changes to the current policy. One commenter encouraged HHS to consider the impact on issuers providing coverage on- versus off-Exchanges, as well as the potential double-counting that may occur between excluding employment taxes from premium while also including them in quality improvement activity (QIA) expenses.

Response: HHS appreciates the comments submitted regarding the treatment of Federal and State employment taxes in the MLR and rebate calculations. We share the concern of some commenters that reversing the policy on the treatment of employment taxes only 1 year after the policy became effective could contribute to instability. We also continue to disagree that the PPACA unambiguously requires exclusion of employment taxes from the MLR and rebate calculations. However, it is our objective to explore and pursue all policy solutions that may help stabilize the health insurance market. Therefore, after reviewing the comments and recommendations, HHS intends to gather data to help analyze the potential impact on consumers and issuers that would result from excluding Federal and State employment taxes from earned premium in the MLR and rebate calculations, and perform additional data analysis to inform whether a modification to the current policy would be appropriate. Specifically, while issuers already report the employment tax amounts together with other taxes on the MLR reporting form, HHS intends to propose changes to the MLR Annual Reporting Form to include a separate line that will show these tax amounts for each issuer. This will provide HHS with more up-to-date and consistent data on employment taxes to more precisely estimate how potential modifications to the current policy may affect issuers and consumers and to determine whether such modifications would likely improve market stability.

2. Allocation of Expenses (§ 158.170)

For a discussion of the proposed amendment to § 158.170(b) regarding the description of the allocation method for quality improvement activity (QIA) expenses and a summary of the comments received and responses provided, please see the preamble to § 158.221. We are finalizing the change as proposed.

3. Formula for Calculating an Issuer's Medical Loss Ratio (§ 158.221)

We proposed amending § 158.221 by adding new paragraph (b)(8) to provide issuers with an option to report quality improvement activity (QIA) expenses as a single fixed percentage of premium amount starting with the 2017 MLR reporting year (for reports to be filed by July 31, 2018). We also proposed conforming amendments to § 158.170(b) (Allocation of expenses) to recognize the new proposed option for reporting QIA expenses.

Consistent with the NAIC's recommendation to HHS,[97] the MLR interim final rule, published on December 1, 2010 (75 FR 74863), allows issuers to include in the MLR numerator expenditures for five categories of activities that improve health care quality. Accordingly, issuers are currently required to report QIA expenditures in alignment with the five separate categories codified in § 158.150(b)(2)(i)–(v). Additionally, § 158.170 requires issuers to use and disclose specific allocation methods to report expenses, including QIA expenditures.

In the course of conducting the MLR audits, HHS observed that the current MLR regulations require a substantial effort by issuers to accurately identify, track and report QIA expenses. HHS has also observed that, between 2011 and 2015, issuers that did report QIA expenses have reported spending, on average, a consistent percentage of premium on total QIA: approximately 0.7 percent in 2011, and 0.8 percent in 2012 through 2015.

Given issuers' relatively low and consistent reported expenditures on QIA and the significant burden associated with identifying, tracking and reporting these expenditures, we proposed adding § 158.221(b)(8) to permit issuers an option to report on their MLR reporting form a single QIA amount equal to 0.8 percent of earned premium in the relevant State and market, in lieu of tracking and reporting the issuer's actual expenditures for QIA, as defined in § 158.150 and § 158.151. The accompanying proposed amendments to § 158.170(b) would require issuers that elect the option to include 0.8 percent of earned premium for QIA expenses to indicate as such when describing the allocation method used for QIA expenses. Issuers that spend more than 0.8 percent of earned premium on QIA would have the option to report the total actual, higher amount spent and, if choosing this option, would have to report QIA in the five categories described in § 158.150(b)(2)(i)–(v), as well as comply with the allocation of expenses requirements established under § 158.170.

We are finalizing this policy as proposed, except that, in response to comments, we are specifying, as described below, how the optional QIA reporting method may be used across affiliated issuers, markets, and years.

Comment: We received comments from consumer and patient advocacy groups, health insurance issuers, States, and individuals regarding the proposal to provide a standardized option to report QIA. Most commenters opposing the proposal stated that the current QIA requirements motivate issuers to invest in improving the health and well-being of consumers, and therefore allowing issuers who spend nothing on QIA to take a standardized credit for QIA would disincentivize issuers from making such investments. Many commenters stated that by giving issuers credit for expenses that issuers may not actually incur, the proposal would result in consumers receiving coverage of a lower value. Some commenters expressed concern that the 0.8 percent standardized option would further provide a competitive advantage to issuers that get credit without investing

[97] National Association of Insurance Commissioners—Model Regulation Service, Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012 and 2013 per Section 2718(b) of the Public Health Service Act (Oct 27, 2010), available at *http://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf.*

in QIA. Many commenters stated that State regulators and consumers are interested in knowing how much and what types of innovative QIA are being implemented, and would lose access to this information under the proposal. These commenters were also concerned that reduced accountability would adversely affect the integrity of the MLR program. One commenter pointed out that premiums tend to increase faster than non-medical expenses so using a flat 0.8 percent may overstate QIA in the future. Most commenters who supported the proposal stated that the current process for identifying, tracking and reporting QIA expenses is burdensome, time consuming and costly. Some commenters indicated that it is hard for issuers to segregate QIA expenses since QIA is ingrained throughout issuers' activities and the current process requires issuers to track individual employees' time spent on a specific task. A few commenters suggested raising the standardized credit to 1.0 percent of premiums, some stated that 0.8 percent would be appropriate, while others contended that 0.8 percent would be excessive. One commenter requested that HHS clarify whether issuers must make an election to use the optional QIA reporting method prior to the plan year; whether it must be elected for a minimum fixed period of years; and the issuer, State, and market aggregation level(s) to which the election applies. One commenter recommended that issuers be allowed to retroactively change the QIA reporting method with respect to the 2 prior years included in the MLR calculation, while another commenter recommended that issuers be allowed to elect the standardized QIA option for only some of their markets. In contrast, another commenter expressed concern that such approach could lead to inadvertent or intentional double-counting, particularly for those issuers that incur QIA expenses at the holding group level, and recommended that HHS require a consistent reporting methodology across all markets at the holding group level and for a minimum of 3 consecutive years. Several commenters requested inclusion of certain other activities in QIA, which we note is beyond the scope of the amendments proposed in the proposed rule.

Response: We reviewed each of the comments and recommendations and are finalizing the amendments as proposed with the following modification. In response to commenters' request for clarification regarding the application of the new QIA reporting option, and in order to address commenters' concerns regarding the impact of the new QIA reporting option on the integrity of the MLR program, we are specifying that issuers and their affiliates that elect the standardized QIA reporting option must apply it consistently across all of their States and markets that are subject to the MLR requirements in section 2718 of the Public Health Service Act. Further, similarly to some other optional MLR reporting provisions,[98] issuers and their affiliates that elect the standardized QIA reporting option must apply this reporting method for a minimum of 3 consecutive reporting years. In addition, we will require all affiliated issuers to elect the same QIA reporting method. These provisions will ensure that the new QIA reporting option is appropriately utilized by issuers to simplify reporting, rather than to inflate the MLR based on the experience of a particular year. Further, in the course of conducting the MLR audits, HHS observed that QIA initiatives are often developed and administered at the parent company level and the costs are then prorated down to each issuer, State, and market segment using complex allocation methods. Therefore, the requirement that the new QIA reporting option be applied in a consistent manner across all States, relevant markets, and affiliates will additionally eliminate gaming incentives for companies to use the standardized 0.8 percent of premium QIA amount for some of their issuers, States, or markets and simultaneously maximize the allocation of the actual QIA costs to their other issuers, States, or markets. This approach is also consistent with the fact that the 0.8 percent of premium threshold was identified based on the average across all issuers, States, and markets. We note that the new QIA reporting method is optional, and does not prevent issuers from continuing to allocate and benefit from reporting the actual QIA expenses for each State and market. While we acknowledge commenters' concerns that the standardized QIA reporting option may in some cases give issuers credit for activities that they do not perform, we note that issuers also have financial incentives to improve the health of their enrollees because healthier populations incur lower medical costs, and reducing the administrative burden associated with tracking QIA will free up funds that issuers can invest in QIA. Additionally, while we recognize that there is variation in QIA spending between different issuers, we continue to believe that 0.8 of earned premium is appropriate based on the average of MLR data over 2011–2015, and that a single nationwide percentage provides the benefit of simplicity and reduces burdens associated with tracking and reporting QIA expenses. As noted previously, issuers will continue to have the option to report the actual expenditures and therefore will retain the ability to take full credit if these expenditures exceed 0.8 percent of premium. With respect to commenters' concern that QIA expenditures may not grow proportionately to premium and that 0.8 percent may overstate issuers' average QIA expenditures in the future, as well as commenters' concern that they may lose access to the detailed QIA data, we also note that presently, issuers continue to report to States QIA data that in some respects are even more detailed than the data previously collected by HHS. Therefore, the public and States retain the ability to access this type of information. In addition, HHS will monitor QIA reporting and review available data, and may modify the QIA reporting policy in the future if HHS determines it to be necessary. Finally, we note this change will also help level the playing field among issuers, since many issuers likely do engage in QIA but currently forego reporting because the burden of analyzing, documenting, tracking, allocating, and reporting QIA expenses exceeds the benefits for MLR purposes.

[98] Such as the reporting of group health insurance coverage with dual contracts in § 158.120(c).

4. Potential Adjustment to the MLR for a State's Individual Market (Subpart C)

We proposed to amend 45 CFR part 158, subpart C to modify the process and criteria for the Secretary to determine whether to adjust the 80 percent MLR standard in the individual market in a State. Because the majority of comments focused on the broader merits of amending subpart C, rather than on the specific sections, we address all comments after summarizing the proposed amendments to each section.

Section 2718(d) of the PHS Act provides that the Secretary may adjust the MLR standard in the individual market if the Secretary determines it appropriate on account of the volatility of the individual market due to the establishment of Exchanges. The MLR December 1, 2010, interim final rule (75 FR 74864) set forth the framework for a State to request such an adjustment and the process and criteria for the Secretary to determine whether to grant a State's request. Subpart C of 45 CFR part 158 specifies that the adjustment request

must be initiated by the State, the adjustment may be granted for up to 3 years at a time, the information that the State must provide to support its request, and the criteria that HHS may consider in making a determination. It also requires the Secretary to invite public comments on the adjustment requests, allows States to hold optional public hearings, and enables States to request reconsideration of adverse determinations.

Because in the current environment, it generally is not the MLR standard in isolation but rather factors that, taken together, can contribute to instability of the individual market in certain States, the current framework in subpart C restricts the States' ability to obtain adjustments to the MLR standard as part of innovative solutions for stabilizing their individual markets. Therefore, as outlined below, we proposed to make amendments throughout subpart C of part 158 to allow for adjustments to the individual market MLR standard in any State that demonstrates that a lower MLR standard could help stabilize its individual market, and to streamline the process for applying for such adjustments to reduce burdens for States and HHS.

a. Standard for Adjustment to the Medical Loss Ratio (§ 158.301)

For the reasons described above, we proposed to amend § 158.301 to permit the Secretary to adjust the individual market MLR standard in any State if the Secretary determines that there is a reasonable likelihood that an adjustment to the 80 percent MLR standard will help stabilize the individual market in that State. We are finalizing the amendments as proposed.

b. Information Regarding the State's Individual Health Insurance Market (§ 158.321)

We proposed to amend § 158.321 to modify the information that a State must submit to the Secretary with its request for an adjustment to the 80 percent MLR standard in its individual market. Specifically, because we sought to make the MLR adjustment process less burdensome on States and make adjustments available to enable States to develop innovative solutions for stabilizing their individual markets, we proposed to remove the requirements that the State must describe the State MLR standard and formula for assessing compliance (§ 158.321(a)), its market withdrawal requirements (§ 158.321(b)), and the mechanisms available to the State to provide consumers with options for alternate coverage (§ 158.321(c)). Additionally, we proposed to redesignate paragraph (d) as paragraph (a) and to revise the redesignated paragraph to describe the information the State must submit regarding the State's individual health insurance market, as outlined below.

We also proposed to replace the requirement previously codified at § 158.321(d)(1) that a State provide detailed product-level enrollment and premium data with a requirement at § 158.321(a)(2) to submit information only on the total number of enrollees (life-years and covered lives) for each type of coverage sold or renewed in the State's individual market. Similarly, we proposed to eliminate the requirement previously codified in § 158.321(d)(1) to submit product-level premium data in favor of the total earned premium data in the proposed § 158.321(a)(1), and to eliminate the § 158.321(d)(1) requirement to submit the issuer's individual market share.

We proposed to continue to require States to include information on total earned premium (proposed § 158.321(a)(1)) and total agent and broker commission expenses (proposed § 158.321(a)(3)) for each type of coverage sold or renewed in the State's individual market, as described in more detail below, as well as the risk-based capital (RBC) level (proposed § 158.321(a)(5)), which, due to the manner in which RBC is calculated, would only be appropriate to report at the issuer level, rather than for each type of coverage. We also proposed to revise the accompanying regulation text for these data elements for readability. We further proposed that State requests should include information on total incurred claims (proposed § 158.321(a)(1)) for each type of individual market coverage described below, in lieu of the previous more burdensome requirement to provide reported and estimated individual market MLRs (§ 158.321(d)(2)(ii) through (iii)).

We proposed to modify these requirements to require States to only include the information for each issuer actively offering individual market coverage. We also proposed to add a new § 158.321(b) to require that a State request include the individual market data required in the proposed new § 158.321(a)(1) through (4) and (6) separately for each issuer actively offering individual market plans in that State group by the following categories, as applicable: On-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140, coverage that meets the criteria for transitional policies outlined in applicable guidance,[99] and non-grandfathered single risk pool coverage, in order to enable the Secretary to assess the situation in the State's individual market and to appropriately evaluate the State's proposal. Proposed new § 158.321(b) would also require the State to report the RBC information at the issuer level for each issuer actively offering coverage in the State's individual market. A State would not be required to provide information on student health insurance coverage as defined in § 147.145 or individual market excepted benefits as defined in § 148.220.

To further reduce the burden on States, we proposed to remove the requirements to provide net underwriting profit for each issuer's total business in the State and after-tax profit and profit margin for the individual market and total business in the State (§ 158.321(d)(2)(vii)), as well as to rename the remaining requirement to provide the individual market ''net underwriting profit'' to ''net underwriting gain'' to more accurately reflect the accounting term (proposed § 158.321(a)(4)). We also proposed to delete the requirement to provide information on estimated MLR rebates (§ 158.321(d)(2)(v)). Additionally, we proposed to revise the language at current paragraph § 158.321(d)(2)(ix), proposed to be redesignated at § 158.321(a)(6), to require the State to provide information not only on notices by issuers covered in § 158.321(a) of market exits, but also the equally or more pertinent issuer notices of beginning to offer coverage in the individual market, as well as ceasing or commencing offering individual market coverage on the Exchange or in specific geographic areas (for example, counties); and to add a new § 158.321(c) to require similar information on issuers not actively offering coverage in the individual market that have indicated an intent to enter or exit the individual market, including ceasing or commencing offering individual market coverage on the Exchange or in specific geographic areas. Lastly, we recognize that in many situations the information proposed to be required in § 158.321(a) will only be available for the preceding calendar year, but we proposed to provide States with an option to also include information for the current year (where available), which may be more

[99] See, for example, CMS ''Insurance Standards Bulletin Series—Information—Extension of Transitional Policy through Calendar Year 2018 (February 23, 2017) available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Extension-Transitional-Policy-CY2018.pdf*.

relevant if a State makes a request in a later part of the year.

We are finalizing the amendments as proposed, with one correction to § 158.321(b) to indicate that the information required in paragraph § 158.321(a)(5) is the only information that must be provided at the issuer level.

c. Proposal for Adjusted Medical Loss Ratio (§ 158.322)

To reduce the burden on States, we proposed to remove paragraphs (a), (c) and (d) of § 158.322, which would remove the requirements for a State to justify how its proposed adjustment was determined, and to estimate rebates that would be paid with and without an adjustment because HHS can make these estimates instead of the State. Consistent with our proposed changes to § 158.301, we proposed to revise § 158.322 to require the State to both provide its proposed, adjusted MLR standard and explain how this proposed standard would help stabilize its individual market. We also proposed to delete current paragraph (b), which requires an explanation of how an adjustment would permit issuers to adjust current business models and practices in order to meet an 80 percent MLR as soon as is practicable, to further reduce burden on States submitting adjustment requests.

We are finalizing the amendments as proposed.

d. Criteria for Assessing Request for Adjustment to the Medical Loss Ratio (§ 158.330)

Section 158.330 lists the criteria that the Secretary may consider in determining whether to approve a State request to adjust the 80 percent MLR standard for the individual market. We proposed amendments throughout the section to reflect the proposal in § 158.301 to allow adjustments if the Secretary determines the adjustment would help stabilize the individual market in that State, and the proposed changes to the information requirements in § 158.321. Specifically, we proposed conforming amendments to the introductory text of § 158.330 to provide that the Secretary may consider the identified criteria when assessing whether an adjustment to the individual market MLR standard would be reasonably likely to help stabilize the individual market in a State that has requested such an adjustment. We proposed to replace the information currently outlined at § 158.330(a)(1)–(4) regarding individual market issuers reasonably likely to exit the State with information regarding the number and financial performance of issuers actively offering individual market coverage on-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage; the number of issuers reasonably likely to cease or begin offering such individual market coverage in the State; and the likelihood that an adjustment would increase competition in the State's individual market, including in underserved areas (proposed § 158.330(a)). We proposed to delete the existing criteria captured at § 158.330(b) related to consideration of the number of individual market enrollees covered by issuers that are reasonably likely to exit the State's individual market absent the requested adjustment because the goal of a State request for adjustment may be to ensure that health insurance coverage is available to all, rather than a certain percentage of, consumers who want it, and that consumers not only have coverage, but also a choice of several issuers. We proposed conforming amendments to the criteria currently captured at § 158.330(c), proposed to be redesignated at § 158.330(b), regarding whether an adjustment might improve consumers' access to agents and brokers. Similar to the proposed amendments to § 158.321 described above to remove the requirement for States to provide information on available mechanisms to provide alternate coverage, we proposed to replace the current criteria outlined at § 158.330(d)(1)–(5) with consideration of information on the capacity of any new issuers or issuers remaining in the individual market to write additional business in the event one or more issuers were to cease or begin offering individual market coverage on Exchanges, in certain geographic areas, or in the entire individual market in the State (proposed § 158.330(c)). We proposed to retain and modify the existing criteria at § 158.330(e), proposed to be redesignated at § 158.330(d), on the impact on premiums charged, and on benefits and cost sharing provided, to consumers by issuers remaining in or entering the individual market in the event one or more issuers were to cease offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State. Finally, we proposed to retain the existing criteria at § 158.330(f), proposed to be redesignated at § 158.330(e), for consideration of any other relevant information submitted by the State.

We are finalizing the amendments as proposed.

e. Treatment as a Public Document (§ 158.341)

Because the format in which States may submit requests for adjustments may not comply with Federal requirements for documents posted on Federal websites, some of these documents may not be able to be posted directly to the applicable Federal website. For example, a State may submit spreadsheets containing data or copies of issuer letters in a format that is not accessible for individuals with visual impairments. However, HHS is committed to transparency and making this information promptly available to the public. HHS is also committed to providing accessible information to members of the public, including individuals with disabilities, and will provide such individuals with accessible copies of documents submitted by States unless doing so would impose an undue burden on the agency. Therefore, we proposed to amend § 158.341 to reflect that Federal requirements for documents posted on Federal websites may not permit these documents to be posted, and to specify that instructions for the public to access information on requests for adjustment to the MLR standard submitted by States will be provided on the Secretary's internet website. We are finalizing the amendments as proposed, with a non-substantive change to the regulatory text.

f. Subsequent Requests for Adjustment to the Medical Loss Ratio (§ 158.350)

We proposed to make conforming amendments to § 158.350, which describes the information that a State must submit with a subsequent request for an adjustment to the MLR standard, to make this information consistent with our proposed changes to § 158.301 and § 158.330. We are finalizing the amendments as proposed.

The following is a summary of the public comments received on these proposals and our responses.

Comment: We received comments from consumer and patient advocacy groups, health insurance issuers, States, and individuals regarding the proposal to modify the process for submission of State requests to adjust the individual market MLR standard and the accompanying criteria for the Secretary to determine whether to adjust the 80 percent MLR standard in the individual market in a State. The majority of comments focused on the merits of the

proposed amendments to subpart C as a whole, rather than offering comments on the specific sections of subpart C. Most commenters opposing the proposals stated that it is unlikely that the MLR standard is a primary driver of market instability and that most insurers already meet or exceed the MLR standard. These commenters stated that lowering the MLR standard would undermine one of the few consumer protections and lead to higher premiums with consumers receiving lower value for those premiums, without strengthening the market. Many commenters focused on the benefits the MLR rule has delivered to consumers and objected to weakening the rule. Several commenters expressed concern that the proposal could lead to discrepancies in standards and access to care. Several commenters disagreed with the proposed elimination or reduction of various requirements on States seeking adjustments due to concerns over the possibility of arbitrary and unjustified requests, inadequately rigorous review, and a decrease in transparency. Most commenters who supported the proposals expressed appreciation that the proposals would give greater flexibility to the States. Some of these commenters stated that a lower MLR standard may have competitive benefits that outweigh potential costs and that States are in the best position to assess that tradeoff. Several commenters stated that the proposals could incentivize issuer expansion and innovation. Additionally, several commenters recommended that States be allowed to only lower (not increase) the MLR standard, and that adjustments not be effective prior to 2020 in order to give issuers time to incorporate adjusted MLR standards into issuers' market participation and pricing decisions. Lastly, one commenter recommended allowing States to adjust the MLR standard for only specific issuers, such as new entrants, while another commenter urged HHS to disallow this in order to not disadvantage established issuers and to avoid encouraging such issuers to leave the market.

Response: We are finalizing the proposed amendments to subpart C as proposed, with one technical correction to § 158.321(b) to indicate that the information required in paragraph § 158.321(a)(5) is the only section that must be provided at the issuer level. We appreciate both the comments highlighting the benefits of the current MLR rule, as well as the comments supporting our efforts to provide more flexibility to States to improve the stability of their markets. We acknowledge the concerns expressed by many commenters that the adjustments to the individual market MLR standard should not undermine consumer protections and that the integrity of the adjustment review process should not be compromised. However, we believe that if States can develop strategies involving an adjusted MLR standard that States can demonstrate would be reasonably likely to lead to a more robust and stable individual market, then this would benefit consumers and ultimately lead to higher quality and more affordable coverage. We note that the amendments to subpart C are not intended to reduce the overall burden of proof on States applying for adjustments, but rather require States to provide more pertinent information and remove duplicative, burdensome requirements, such as those that mandate States submit data that is otherwise publicly available to both HHS and consumers. Given that the goal of the amendments to subpart C is to provide States the flexibility to innovate and pursue the best solutions for their markets, we believe that it would be inconsistent to impose up-front restrictions on how much or what direction of an adjustment a State may seek. For the same reason, we will determine the effective date for each adjustment in consultation with the respective State and based on the timing of the request submitted by the State, but will, as appropriate, take commenters' recommendations on the proposed rule into consideration when making those determinations. We further clarify that a State should include an effective date and duration (for up to 3 MLR reporting years [100]) for the requested adjustment to the individual market MLR standard as part of its proposal. In addition, we note there will be opportunities for public comment on individual State adjustment requests. Sections 158.342 and 158.343 are being retained in their current form, which require the Secretary to invite public comment on State adjustment requests and provide for optional State public hearings, respectively. Lastly, because we interpret the statute as only permitting the Secretary to adjust the MLR standard for the entire individual market within a State, we are not able to allow issuer-specific adjustments within a State. However, we note that there are several other provisions in the MLR regulations that are designed to recognize the special circumstances of smaller and newer plans, and provide incentives for issuers that contemplate entering a market. These include the credibility adjustment for smaller issuers in § 158.323 and the options to defer MLR and rebate calculation for newer business in § 158.121 and to limit the total rebate payment in § 158.240(d).

[100] See 45 CFR 158.311.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 12. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicited comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[101] Table 11 in this final rule presents the mean hourly wage (calculated at 100 percent of salary), the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor

[101] See May 2016 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at *https://www.bls.gov/oes/current/oes_nat.htm*. For State Government Employees see NAICS 999200—State Government, excluding schools and hospitals (OES Designation) *https://www.bls.gov/oes/current/naics4_999200.htm*.

of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 11—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation title	Occupational code	Mean hourly wage ($/hr.)	Fringe benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Business operation specialist *	13–1199	$31.59	$31.59	$63.18
Operations Manager	11–1021	58.70	58.70	117.40
Software Developers, Systems Software	15–1133	53.17	53.17	106.34
Actuary	15–2011	54.87	54.87	109.74
Actuary *	15–2011	40.41	40.41	80.82
Financial Examiner *	13–2061	33.02	33.02	66.04
Financial Analyst *	13–2051	34.39	34.39	68.78
Financial Manager *	11–3031	45.83	45.83	91.66
Lawyer *	23–1011	44.87	44.87	89.74
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43–6014	17.38	17.38	34.76
Commissioner **		58.45	58.45	116.90
Market Research Analyst	13–1161	33.95	33.95	67.90
Medical Records Technician	29–2071	19.93	19.93	39.86
Psychiatrist	29–1066	96.26	96.26	192.52

* Denotes occupations where wages were obtained for State Government employees (*https://www.bls.gov/oes/current/naics4_999200.htm*).
** Data on compensation of State Insurance Commissioners collected by the Council of State Governments and compiled by Ballotpedia (*http://www.ballotpedia.org*). The wage data used in the burden estimates include the cost of fringe benefits and the adjusted hourly wage.

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are finalizing our proposal to allow State regulators to request a reduction, beginning for the 2020 benefit year, to risk adjustment transfers in the individual, small group or merged markets. We are finalizing the requirement for any State requesting this reduction to otherwise applicable transfers to submit its request with the supporting evidence and analysis to HHS identifying the State-specific factors that warrant the adjustment to more precisely account for the differences in actuarial risk in the State's individual, small group or merged market. Additionally, the State must submit supporting evidence and analysis demonstrating the reduction percentage requested is appropriate. This evidence and analysis justifying the percentage requested must either demonstrate the set of factors and the percentage by which those factors warrant an adjustment to more precisely account for the differences in actuarial risk in the State's individual, small group or merged market compared to the national norm, or it must demonstrate the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer or issuers' reduced payments. States are required to submit the requests with the supporting evidence and analysis by August 1st, 2 calendar years prior to the beginning of the applicable benefit year (for example, August 1, 2018, for the 2020 benefit year). The burden associated with this requirement is the time and effort for the State regulators to submit its request and supporting evidence and analysis to HHS. We are updating the burden estimates from those proposed based on the State request and supporting evidence and analysis requirements we are finalizing in this rule. We estimate submitting the request and supporting evidence and analysis will take a business operations specialist 40 hours (at a rate of $63.18 per hour) to prepare the request and 20 hours for a senior manager (at a rate of $117.40 per hour) to review the request and transmit it electronically to HHS. We estimate that each State seeking a reduction will incur a burden of 60 hours at a cost of approximately $4,875 per State to comply with this reporting requirement (40 hours for the insurance operations analyst and 20 hours for the senior manager). Although we are unable to precisely estimate the number of States that will make this request, we expect that no more than 25 States will make these requests annually, resulting in a total annual burden of approximately 1,500 hours with an associated total cost of $121,880. We published a revised information collection approved under OMB control number 0938–1155: Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals, for comment on December 28, 2017, and intend to update it to account for this change in burden.

C. ICRs Regarding Risk Adjustment Data Validation (§ 153.630)

We finalize that, beginning with 2017 benefit year risk adjustment data validation, issuers with 500 billable member months or fewer Statewide that elect to establish and submit data to an EDGE server will not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. We note that, beginning with 2018 benefit year risk adjustment data validation, these issuers will not be subject to random sampling under the materiality threshold discussed below, and will continue to not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. As 2016 benefit year risk adjustment data validation will be another pilot year, we are also finalizing the postponement of the application of the materiality threshold to the 2018 benefit year. Under this policy, all issuers of risk adjustment covered plans will be required to conduct an initial validation audit for the 2017 benefit year risk adjustment data validation, other than issuers with 500 billable member months or fewer Statewide as discussed above. Beginning with the 2018 benefit year, issuers below the $15 million premium materiality threshold will not be

required to conduct an initial validation audit every year, but rather, HHS will conduct random and targeted sampling under which issuers below the materiality threshold would be subject to an initial validation audit approximately every 3 years.

HHS estimates that not requiring issuers that have 500 or fewer billable member months Statewide to conduct an initial validation audit beginning in the 2017 benefit year will exempt 50 issuers from an initial validation audit and reduce administrative costs for each issuer by 828 hours with an estimated cost reduction on average of up to $100,000. The total burden reduction for all 50 issuers will be 41,400 hours with an associated reduction in cost of $3,520,000. The postponement of the effectiveness of the materiality threshold to the 2018 benefit year will not impact issuer burden relative to previous estimates for the risk adjustment data validation program included in the 2014 and 2015 Payment Notices, particularly given that the program has been converted to a pilot for the first 2 years of operation. We are revising the current information collection approved under OMB control number 0938–1155: Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals, to account for this reduction in burden.

For risk adjustment data validation, HHS requires issuers to document mental and behavioral health records included in audit sampling. Without the necessary mental and behavioral health information for each sample, the diagnosis code for an applicable enrollee cannot be validated and, therefore, it would be rejected during risk adjustment data validation.

Because providers may be prevented by some State privacy laws from furnishing a full mental health or behavioral health record, we are amending § 153.630(b)(6) to allow issuers an additional avenue to achieve compliance with data validation requirements by permitting the submission of mental or behavioral health assessments for risk adjustment data validation in the event that a provider is subject to State privacy laws that prohibit the provider from providing HHS with a complete mental or behavioral health record. For risk adjustment data validation purposes, to the extent permissible under applicable Federal and State privacy laws, an assessment should contain: (1) The enrollee's name; (2) sex; (3) date of birth; (4) current status of all mental or behavioral health diagnoses; and (5) dates of service. To submit a mental or behavioral health assessment, an issuer must ensure that it is accompanied by an attestation from the provider that applicable State privacy laws prevent him or her from providing the complete mental or behavioral health record.

HHS expects that this provision may affect 10 percent of issuers or approximately 70 issuers in States with stricter privacy laws on medical records. Based on our experience with the first pilot year risk adjustment data validation audits, we estimate that approximately 40 enrollees in any initial validation audit sample of 200 enrollees could be affected. Since providers routinely prepare mental or behavioral health assessments to validate diagnoses, we believe the slight additional burden is the time it would take to seek patient consent to provide the assessment, in States that require such permission, to review and edit the preexisting assessment for each medical record to include the data elements specified in § 153.630(b)(6), and to attest that relevant State privacy laws prohibit him or her from providing the complete mental or behavioral health record.

Comment: Several commenters stated that obtaining patient consent and provider attestations for mental or behavioral health assessments would impose a significant administrative, professional, and personal burden on issuers, providers, and patients, while one commenter stated that this flexibility could reduce administrative burden if issuers could develop a standard form for physicians to sign.

Response: As noted above, HHS believes that the policy to permit the use of existing mental or behavioral health assessments may result in a slight increase in the burden on issuers and providers, primarily due to the new provider attestation requirement.

We estimate it will take a medical records technician (at an hourly rate of $39.86) 15 minutes to obtain consent from each patient, or approximately 10 burden hours at an estimated cost of $399 per issuer. In addition, we estimate a qualified licensed provider (psychiatrist, at an hourly rate of $192.52) will need 45 minutes to prepare an abbreviated assessment and sign an attestation, for a total of $144 per enrollee, or $5,776 per issuer. Therefore, for 40 patients, the total burden per issuer for the provider to obtain consent from each patient and prepare an abbreviated assessment and signed attestation will be 40 hours and approximately $6,174. The aggregated burden for the estimated 70 affected issuers will be 2,800 hours and approximately $432,194. We are revising the current information collection approved under OMB Control Number 0938–1155: Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals, to account for this additional burden.

D. ICRs Regarding Health Insurance Issuer Rate Increases: Disclosure and Review Requirements—Applicability (§ 154.103)

We are finalizing the proposal to exempt student health insurance coverage as defined in § 147.145 from the Federal rate review requirements. Because we will no longer be reviewing the reasonableness of rate increases for student health insurance coverage, we expect to collect less information for the 2019 plan or policy year than collected for previous years. This will reduce burden related to the submission and review for issuers and States. We estimate that 75 student health insurance issuers will no longer be required to submit rate increases to HHS. We estimate that each rate review submission takes 11 hours for an actuary (at a rate of $109.74 per hour) to prepare, and that each issuer will submit an average of 2.5 plans, at an estimated annual cost of $3,018, resulting in a total reduction in the annual burden to issuers of approximately 2,063 hours and an associated reduction in cost of approximately $226,339. We estimate that States will no longer submit rate increases for 188 student health insurance plans to HHS. We estimate a reduction in burden to States of one hour per plan for an actuary (at a rate of $80.82 per hour) to prepare and electronically submit the appropriate materials, for a total reduction in burden of approximately 188 hours annually with an associated cost reduction of approximately $15,194. We will revise our current burden estimate approved under OMB control number 0938–1141: Rate Increase Disclosure and Review Reporting Requirements, to reflect the reduced burden on States and issuers.

E. ICRs Regarding Rate Increases Subject To Review (§ 154.200)

We are finalizing our proposal to establish a 15 percent Federal default threshold for reasonableness review. We expect this to reduce burden for issuers because Part II of the Rate Filing Justification (Consumer Justification Narrative) is only required for increases that meet or exceed the threshold. In the 2019 plan year, we estimate that the number of written justifications that will be submitted will decrease by approximately 125 submissions. That estimate is based on data from the 2018 plan year. We reached this estimate by counting the number of submissions

with a product subject to review due to an increase between 10 percent and 15 percent. Specifically, CMS received 786 submissions for the 2018 plan year; 579 of those included a rate increase at or above 10 percent; while 454 of those included a rate increase at or above 15 percent, resulting in 125 submissions falling between 10 percent and 15 percent.

We estimate that each written justification will require 1.5 hours for an actuary (at a cost of $109.74 per hour) to prepare and electronically transmit the documentation. Therefore, the annual burden for issuers will be reduced by 187.5 hours, with an estimated annual savings of $20,576.

As stated above, we estimate 125 fewer submissions with rate increases subject to review. Assuming that States adopt the Federal default threshold, we expect the number of State reviews will decrease by 123 submissions.[102] We estimate that each State review will require 38.5 hours of work by an actuary (at a cost of $80.82 per hour). Therefore, the State burden will decrease by approximately 4,735.5 hours, with an estimated annual savings of $382,723.

We will revise our current burden estimate approved under OMB control number 0938–1141: Rate Increase Disclosure and Review Reporting Requirements, to reflect the reduced burden on issuers.

F. ICRs Regarding the Small Business Health Options Program (SHOP)

We are finalizing the proposals granting additional flexibilities, effective on the effective date of this rule and applicable for plan years beginning on or after January 1, 2018, to SHOPs, to qualified employers and employees enrolling in SHOP plans, and to participating QHP issuers and SHOP-registered agents and brokers in how they interact with a SHOP. Under the proposals being finalized throughout this document, SHOPs will no longer be required to provide enrollment, premium aggregation functions, and online enrollment functionality through a SHOP website, and the FF–SHOPs and SBE–FPs for SHOP, will no longer continue to perform these functions. Instead, small groups will enroll in a SHOP plan through a SHOP-registered agent or broker or through a participating QHP issuer participating in a SHOP. FF–SHOPs will follow the approach as outlined in this final rule. SBEs will have the flexibility to operate their SHOP in a way that meets the needs of their State and complies with the regulatory flexibilities outlined herein.

Under the proposals being finalized in this rule several pieces of information currently being collected by a SHOP may no longer be collected by a SHOP, or, the way in which the information is collected may change. For example, employers, employees, and agents and brokers may be required to provide the information currently collected by a SHOP to an issuer for the purposes of enrollment in a SHOP plan. A SHOP, like the FF–SHOPs and SBE–FPs for SHOP, however, will not be the entity collecting the information and the Federal government thus will experience a reduction in burden. Under the new regulatory flexibilities being finalized and described throughout this rule, employers and employees will no longer be required to visit a SHOP website in order to enroll in a SHOP plan and a SHOP will no longer be required to have the capability or the need to collect enrollment information. Employers will however, be required to apply to the SHOP to obtain an eligibility determination, as described in § 155.710, at which point the employer will be requested to provide: (1) Employer name and address of employer's locations; (2) Information sufficient to confirm the employer is a small employer; (3) Employer Identification Number (EIN); and (4) Information sufficient to confirm that the employer is offering, at a minimum, all full-time employees coverage in a QHP through a SHOP. Under current regulations, the employer provides, and a SHOP collects, this information as part of enrolling in a SHOP QHP through a SHOP. HHS previously estimated that an employer needed two hours to complete the eligibility determination when it was included as part of enrolling in a SHOP QHP and that 6,000 employers will complete an application annually to determine their eligibility through a SHOP website. Based on these criteria, HHS estimated that the total annual burden for 6,000 employers was 12,000 hours, with a total annual cost of $561,240 to complete the SHOP application and eligibility determination process. With the new regulatory flexibilities being granted to SHOPs, HHS estimates that for each employer, an administrative assistant will need less than 5 minutes (at rate of $34.76 per hour) to complete the required eligibility determination. Under the new flexibilities, employers will also no longer be required to create an account on an FF–SHOP website in order to complete the eligibility determination or enroll in a SHOP QHP. Therefore, HHS estimates that it will cost an employer approximately $3 to complete an eligibility determination. Assuming that 6,000 employers will complete an eligibility determination, HHS estimates that the total annual burden will be approximately 500 hours, with an estimated total cost of $17,400. This will result in a net burden reduction of 11,500 hours and a net cost reduction of approximately $543,840 annually. Under § 157.206(e)(1), employers will be responsible for submitting a new eligibility determination or, submitting a notice of withdrawal, in the event the group experienced a change that will impact the group's eligibility to participate in a SHOP. Under § 157.206(e)(2), employers will also be required to notify their QHP issuer(s) of a determination of ineligibility. Finally, employers will also, under § 157.206(e)(3) be required to notify their issuers of their intent to no longer participate in a SHOP. While these proposals will require employers to communicate with issuers in ways they do not under current SHOP enrollment practices, HHS does not anticipate that these practices will increase the burden on employers as they, under current practice, must notify the SHOP of changes in eligibility and termination. Although the policy in § 155.716 imposes an information collection requirement, the information that will be collected is no different from what is already approved under OMB control number 0938–1193: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in the Small Business Health Options, and therefore we are not revising the information collection at this time.

Employees, under § 155.716 will not experience an increase in burden. Under the policies described throughout this final rule, employees will no longer be required to visit an FF–SHOP website to create an account, or, for any application or enrollment purpose, but they may need to provide similar information to an agent or broker or issuer as a condition of enrollment into a SHOP QHP. HHS previously estimated that 60,000 employees will complete an application annually, each spending approximately one hour to complete an online application through an FF–SHOP website. The estimated annual burden was 60,000 hours with an annual cost of $1,025,400. With the finalized flexibilities to a SHOP as described in this rule, HHS predicts that the burden on employees to complete an online application will shift as no application

[102] For the 2018 plan year, CMS reviewed two submissions proposing a rate increase between 10 percent and 15 percent.

will be provided through a SHOP website, but the information may be required by an agent or broker or an issuer in order for the employee to complete an enrollment into a SHOP QHP. The proposals described throughout this final rule will allow agents and brokers and issuers to enroll consumers in SHOP plans using the channels they are most familiar with, potentially reducing the burden of enrolling SHOP groups. This information collection is currently approved under OMB control number 0938–1194: Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program. Therefore, we are not revising the information collection at this time.

Sections 155.705, 155.715, 155.720, 155.725, require SHOPs to generate certain notices. These notices may include: (1) Notices of annual election periods; (2) notices to employers of employee coverage terminations; (3) notices of application inconsistencies; (4) notices of appeal rights and instructions; (5) notices of employee and employer eligibility; (6) notices of employer withdrawal; (7) (in FF–SHOPs only) notices to employees if a dependent turns 26 and is no longer eligible for dependent coverage; (8) billing invoices, successful and unsuccessful payment confirmation notices; and (9) past due payment notices. In prior guidance, HHS previously estimated costs for paper notices in an FF–SHOP. In that estimate, HHS assumed that 80 percent of enrollees requested electronic notices and 20 percent of enrollees requested paper notices. HHS estimated that mailing paper notices costs a SHOP Exchange $0.53 per notice. HHS determined that SHOPs sent approximately 48,000 notices to enrollees when—(1) A dependent became ineligible to remain on the plan; (2) successful payment was processed; and (3) a payment was unsuccessful in the last year. Assuming that 20 percent of enrollees will opt to receive paper notices instead of electronic notifications, HHS estimated that approximately 9,600 notices will be sent, costing FF–SHOPs approximately $5,088. Under the flexibilities being finalized, SHOPs will only be required to send notices of employer eligibility and appeals. This cost will not directly be transferred to issuers as issuers may already be required to send such notices per other applicable State and Federal law. This collection is currently approved under OMB control number 0938–1207: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment. Issuers will be required to collect premiums, as premium aggregation functions will no longer be provided by the SHOPs that take advantage of the new flexibilities. HHS does not anticipate a significant increase of issuers' burden in this scenario, as it is not significantly different from their current operating practices.

G. ICRs Regarding Essential Health Benefits (§ 156.111(e))

In the rule, we are finalizing at § 156.111(e) to revise the collection of data for selection of States' EHB-benchmark plans for plan years beginning on or after January 1, 2020. This proposal includes the documentation that States would be required to submit if the State chooses to change its EHB-benchmark plan. For this purpose, we are amending the currently approved information collection (OMB Control Number: 0938–1174) to reflect the finalized policy in this rule. Because § 156.111(e) is replacing the current data collection requirements at § 156.120, we are updating the current EHB-benchmark plan selection to account for the new regulation and any associated burden with this requirement that falls on those States that choose to reselect their EHB-benchmark plan. Under the previous benchmark plan selection policy, 29 States selected one of the 10 base-benchmark plan options and 22 States defaulted. The previous benchmark plan policy did not allow for States to make an annual selection. The regulation allows States the opportunity to modify their EHB-benchmark plans annually. The regulation also does not require the State to respond to this ICR for any year for which they did not change their EHB-benchmark plan. As such, for purposes of the new EHB-benchmark plan selection options finalized in this rule, we estimate that 10 States would choose to make a change to their EHB-benchmark plans in any given year (total of 30 States over 3 years within the authorization of this ICR) and respond to this ICR.

To select a new EHB-benchmark plan, we require at § 156.111(e)(1) that the State provide confirmation that the State's EHB-benchmark plan selection complies with certain requirements, including those under § 156.111(a), (b), and (c). To complete this requirement, we estimate that a financial examiner will require 4 hours (at a rate of $66.04 per hour) to fill out, review, and transmit a complete and accurate document. We estimate that it costs each State $264 to meet this reporting requirement, with a total annual burden for all 10 States of 40 hours and an associated total cost of $2,642.

Second, we require at § 156.111(e)(2) that the State submit an actuarial certification and associated actuarial report of the methods and assumptions when selecting options under § 156.111(a). Specifically, we are finalizing at § 156.111(b)(2)(i) and (ii) that a State's EHB- benchmark plan must provide a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, and that the State's EHB-benchmark plan must not exceed the generosity of the most generous among a set of comparison plans. The actuarial certification that is being collected under this ICR is required to include an actuarial report that complies with generally accepted actuarial principles and methodologies. This estimate includes complying with all applicable ASOPs. For example, ASOP 41 on actuarial communications includes disclosure requirements, including those that apply to the disclosure of information on the methods and assumptions being used and ASOP 50 contains information on determining MV and AV. In accordance with ASOP 41, we would expect that the actuarial report is based on a data analysis that is reflective of an appropriate population. The actuarial certification for this requirement is provided in a template and includes an attestation that the standard actuarial practices have been followed or that exceptions have been noted. The signing actuary is required to be a Member of the American Academy of Actuaries.

We estimate that an actuary, who is a member of the American Academy of Actuaries, requires 18 hours (at a rate of $80.82 per hour) on average for § 156.111(e)(2). This includes the certification and associated actuarial report from an actuary to affirm, in accordance with generally accepted actuarial principles and methodologies, that the State's EHB-benchmark plan provides a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within an EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, and that the State's EHB-benchmark plan definition does not exceed the generosity of the most generous among the set of comparison plans. We are also finalizing a document entitled *Example*

of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii)[103] that provides an example of a method an actuary could use to develop the actuarial certification and associated report at § 156.111(e)(2) for both the typical employer plan and comparison plan standards.

For these calculations, the actuary needs to conduct the appropriate calculations to create and review an actuarial certification and associated actuarial report, including minimal time required for recordkeeping. The precise level of effort for the actuarial certification and associated actuarial report under § 156.111(e)(2) will likely vary depending on the State's approach to its EHB-benchmark plan and this certification requirement. For example, as described in the *Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii),* to reduce the burden of these standards, the actuary may want to consider using the same plan for both the generosity and the typicality tests, provided that the plan meets the standards at both § 156.111(b)(2)(i) and (ii). For example, the actuary may only need to do one plan comparison for the purposes of both of these certification requirements. Specifically, the actuary could use the same plan, such as the State's EHB-benchmark plan used for the 2017 plan year. That plan would, by definition, be a ''Comparison Plan.'' Because the State's EHB-benchmark plan used for the 2017 plan year would simply be one of the State's base-benchmark plans, supplemented as necessary under § 156.110, that plan also could be used for purposes of determining typicality, as a proposed State EHB-benchmark plan that was equal in scope of benefits to the State's EHB-benchmark plan used for the 2017 plan year within each EHB category at § 156.110(a) would be equal to or greater in scope of benefits within each EHB category at § 156.110(a) than the base-benchmark plan underlying the EHB-benchmark plan used for the 2017 plan year, to the extent of the required supplementation. We estimate that a financial examiner will require 1 hour (at a rate of $66.04 per hour) to review, combine, and electronically transmit these documents to HHS, as part of a State's EHB-benchmark plan submission.

We increased the estimated burden hours from 16 hours to 18 hours for the actuary to complete the actuarial certification and associated report in recognition of the extension of the generosity standard and in recognition that the definition of typical employer plan may require the actuary to determine whether the typical employer plan meets MV requirements. We are also increasing the estimated number of States that need to respond to this section of the ICR from 7 to 10 since the typical employer plan standard and the generosity standard applies to all State's EHB-benchmark plan options at § 156.111(a). We estimate that each State incurs a burden of 19 hours with an associated cost of $1,520.80 with a total annual burden for 10 States of 190 hours at associated total cost of $15,208. We did not receive comments on this specific estimate.

Third, we require at § 156.111(e)(3) each State to submit its proposed EHB-benchmark plan documents. The level of effort associated with this requirement will depend on the State's selection of the EHB-benchmark plan options under the regulation at § 156.111(a). However, for the purposes of this estimate, we estimate that it requires a financial examiner (at a rate of $66.04 per hour) 12 hours on average to create, review, and electronically transmit the State's EHB-benchmark plan document that accurately reflects the benefits and limitations, including medical management requirements and a schedule of benefits, resulting in a burden of 12 hours and an associated cost of $792, with a total annual burden for all 10 States of 120 hours and an associated cost of $7,925. The burden for producing these documents is significantly higher than previous estimates because the previous data collection generally only required the State (or issuer) to transmit the selected benchmark plan document. In contrast, in some cases, the § 156.111(a) may result in the State needing to create a completely new document or significantly modify the current document to represent the plan document. Additionally, this estimate of 12 hours also includes the burden necessary for a State selecting the option at § 156.111(e)(3) where the State is required to submit a formulary drug list for the State's EHB-benchmark plan in a format and manner specified by HHS. Specifically, the burden for the State selecting this option is also likely to vary as the State could use an existing formulary drug list or create its own formulary drug list separately for this purpose. To collect the formulary drug list, the State is required to use the template provided by HHS and submit the formulary drug list as a list of RxNorm Concept Unique Identifiers (RxCUIs).

Section 156.111(e)(4) requires the State to submit the documentation necessary to operationalize the State's EHB-benchmark plan. This reporting requirement includes the EHB summary file that is currently posted on CCIIO's website, used as part of the QHP certification process, and integrated into HHS's IT Build systems that feed into the data that is displayed on *HealthCare.gov*. While this document is not a new document, the burden associated with this document is new for States. We estimate that it requires a financial examiner 12 hours, on average, (at a rate of $66.04 per hour) to create, review, and electronically submit a complete and accurate document to HHS resulting in a burden of 12 hours and an associated cost of $792, with a total annual burden for all 10 States of 120 hours and an associated cost of $7,925.

Under the previous policy, the burden estimates 226 respondents per year, for a total yearly burden total of 165 annual burden hours and a total annual associated cost of $8,094 to meet these reporting requirements. Under the new policy related to EHB, we estimate that the total number of respondents will be 10 per year, for a total yearly burden of 470 hours and an associated cost of $33,699 to meet these reporting requirements. The estimated burden associated with the changes represents an increase of 305 hours (increase from 165 hours to 470 hours) and an annual costs increase of $25,605 (from $8,094 to $33,699) over the previously approved information collection (OMB Control Number: 0938–1174).

As part of the update to this OMB control number: 0938–1174, we also sought comment on requirements for SADPs to submit voluntary reporting. This collection includes data on whether the issuer intends to offer SADP coverage, the anticipated Exchange market in which coverage will be offered, and the State and service area in which the issuer offers coverage. The burden associated with meeting this requirement includes the time and effort needed by the issuer to report on whether it intends to offer SADP coverage. We estimate that it will take one half hour for a health insurance issuer to meet this reporting requirement. We estimate that approximately 175 issuers will respond to this data collection. Therefore, we anticipate that the reporting

[103] *Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii) is* available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html.*

requirement will require a market research analyst one half-hour annually to identify and submit the responsive records to HHS (at a rate of $67.90 per hour), for a total cost of $34 a year per reporting entity. This will result in an annual burden of 87.5 hours for all 175 issuers and a resulting estimated annual cost of $5,941. OMB approvals are issued for 3 years; therefore, the aggregate burden for 3 years will be approximately 263 hours with an associated cost of approximately $17,824. We did not receive comments on these estimates.

Lastly, as part of the update to this OMB control number: 0938–1174, we are adding an information collection request to this ICR to account for the finalized policy at § 156.115(b)(2)(ii) that allows the State the option to notify HHS that the State will allow substitution between EHB categories of benefits, beginning with the 2020 plan year. Specifically, § 156.115(b)(2)(ii) will allow issuers to substitute benefits only when the State in which the plan will be offered permits such substitution and notifies HHS of its decision to allow substitution between categories. We anticipate that States will notify HHS through the same means the States will notify HHS of an updated EHB-benchmark plan selection under § 156.111 and we intend to provide a preformatted response for States to use to provide the notification to HHS. To provide notification under § 156.115(b)(2)(ii), we estimate that it will require a financial examiner ½ hour, on average, (at a rate of $66.04 per hour) to review and electronically submit a notification to HHS. Furthermore, we estimate that at most 5 States will want to allow the flexibility for their issuers to substitute between categories under § 156.115(b)(2)(ii). While this aspect of the ICR is not subject to the PRA because we estimate that no more than 5 States will be affected annually, we nonetheless provide a total annual burden estimate for § 156.115(b)(2)(ii), which is 2.5 hours and a total associated cost of $165.

H. ICRs Regarding Medical Loss Ratio (§§ 158.170, 158.221, 158.320–323, 158.340, 158.346, and 158.350)

We are amending § 158.221 to allow issuers the option to report quality improvement activity expenses as a single fixed percentage of premium amount beginning with the 2017 MLR reporting year (that is, for reports filed by July 31, 2018), and making conforming amendments to § 158.170. We do not anticipate that implementing this provision will require significant changes to the MLR annual reporting form and the associated burden. In addition, while we are not making changes to § 158.162, pursuant to public comments, we intend to make a change to the MLR annual reporting form in order to collect the information on issuers' employment taxes separately from other taxes. We do not anticipate that implementing this provision will significantly change the reporting burden either, as issuers already include this information on the reporting form, and would simply have to include it on a different line on the form. The burden related to this collection is currently approved under OMB control number 0938–1164; Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements.

We are also amending subpart C to modify the data and narratives which a State must submit as part of the State's request for an adjustment to the MLR standard in the individual market for that State. There is no standardized application form associated with a State's request, but each request must contain certain data elements in order to receive consideration by the Secretary, which are described in §§ 158.320–158.323, 158.340, 158.346, and 158.350. The burden related to the proposed requirements was previously approved under OMB control number 0938–1114, Medical Loss Ratio (IFR) Information Collection Requirements and Supporting Regulations; the approval expired in 2014. We intend to reinstate this information collection, with modifications to reflect our finalized revisions to subpart C of part 158. The proposed rule (82 FR 51052), published on November 2, 2017, served as the 60-day notice to afford the public an opportunity to comment on this collection of information requirement.

We are eliminating collection of the following information from a State requesting an adjustment: The State MLR standard and formula for assessing compliance (§ 158.321(a)), its market withdrawal requirements (§ 158.321(b)), and the mechanisms available to the State to provide consumers with options for alternate coverage (§ 158.321(c)); as well as the net underwriting profit for the total business in the State and the after-tax profit and profit margin for the individual market and total business in the State (§ 158.321(d)(2)(vii)), and the estimated rebate (§ 158.321(d)(2)(v)) of each issuer with at least 1,000 enrollees in the State. We expect these amendments to reduce the burden on States seeking an adjustment. We are also replacing the requirement that a State requesting an adjustment must submit enrollment and premium data for every individual market issuer at the product level (§ 158.321(d)(1)) and the reported and estimated MLRs (§ 158.321(d)(2)(ii) and (iii)) for issuers with at least 1,000 enrollees, with total enrollment (life-years and covered lives), premium, and total incurred claims for only active individual market issuers, separately for five types of individual market coverage: On-Exchange plans, off-Exchange plans, grandfathered health plans as defined in § 147.140, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage. States will not be required to provide information on student health insurance coverage as defined in § 147.145 or excepted benefits as defined in § 148.220. We expect these amendments to result in a net reduction in burden on States seeking an adjustment. We will continue to collect data on total agents' and broker's commission expenses and net underwriting gain (proposed to be redesignated from § 158.321(d)(2)(iv) and (vi) to § 158.321(a)(3) and (4), respectively) for only active individual market issuers, but separately for the five types of coverage described above. We will also continue to collect information on risk-based capital levels (proposed to be redesignated from § 158.321(d)(2)(viii) to § 158.321(a)(5)) at the issuer level. While the amendments will require more breakdown of the data than § 158.321 previously required, in most States there are more issuers with at least 1,000 enrollees than there are active issuers in the individual market, and consequently we expect that these amendments will have no net impact on the burden. Additionally, we are updating § 158.321(d)(2)(ix) to collect more specific information on issuer notices to the State of changes to participation in the State's individual market, rather than focusing exclusively on notices to exit the individual market. We do not expect this amendment to have an appreciable impact on the burden. We are further eliminating the requirement that a State requesting an adjustment provide information explaining and justifying how its proposed adjustment was determined and estimating rebates that would be paid with and without an adjustment (§ 158.322(a), (c), and (d)); as well as replacing what information a State must provide pursuant to § 158.322(b) with a requirement to explain how the adjustment would help stabilize the State's individual market. We expect these amendments to reduce the burden. Lastly, we have updated what information a State must submit with a

subsequent request for adjustment pursuant to § 158.350. We do not expect this amendment to change the burden.

Based on preliminary data analysis and previous State requests for adjustments, we estimate that approximately 22 States will submit applications in the first year. We estimate that it will take approximately 140 hours on average for each State to complete the application, including gathering and analyzing data, synthesizing information, and developing a proposal for an adjusted MLR standard. Specifically, we assume that the application will take a financial analyst approximately 96 hours (at a rate of $68.78 per hour), an actuary 6 hours (at a rate of $80.82 per hour), a financial manager 10 hours (at a rate of $91.66 per hour), a lawyer 24 hours (at a rate of $89.74 per hour), and the insurance commissioner 4 hours (at a rate of $116.90 per hour) to assemble and review the various components of the application, resulting in a total burden for each State of 140 hours with an associated cost of $10,626 per response, representing an estimated total burden reduction of 45 hours per response. The documents will be submitted electronically at minimal cost. We estimate that the total burden for 22 States to submit a request for an adjustment to the individual market MLR standard will be 3,080 hours with an associated cost of approximately $233,767, with an estimated net total reduction in burden of 620 hours. We recognize that this burden may vary between States, as some States may have better access to the required application information elements, while other States may have to seek some of the required information from health insurance issuers in their States, which could increase their burden. Some States may, if providing the requested information is an undue burden, ask the Secretary to consider their application without some of the information elements. We received a few comments that generally questioned whether the burden on States related to the information collection requirements prior to the finalized amendments may have been overstated, but that did not specify the basis for such concerns and did not relate to the estimates for the revised information collection requirements. We also received one comment that agreed with the estimates for the revised information collection.

I. Summary of Annual Burden Estimates for Final Requirements

TABLE 12—FINAL ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($)
§ 153.320	0938–1155	25	25	60	1,500	$121,880.00	$121,880.00
§ 153.630(b)(6)	0938–1155	70	2,800	1	2,800	432,194.00	432,194.00
§ 156.111(e)(1)	0938–1174	*10	10	4	40	2,641.60	2,641.60
§ 156.111(e)(2)	0938–1174	*10	10	19	190	15,208.00	15,208.00
§ 156.111(e)(3)	0938–1174	*10	10	12	120	7,924.80	7,924.80
§ 156.111(e)(4)	0938–1174	*10	10	12	120	7,924.80	7,924.80
§ 156.115(b)(2)(ii)	0938–1174	*5	5	0.5	2.5	165.10	165.10
§ 156.150	0938–1174	175	175	0.5	87.5	5,941.25	5,941.25
§§ 158.320–323, 158.340, 158.346–350	0938–1114	22	22	140	3,080	233,766.72	233,766.72
Total		302	3,067		7,940	827,646.27	827,646.27

*Denote the same entities. For purposes of calculating the total, the value is used only once.

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 12.

J. Submission of PRA-Related Comments

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

To obtain copies of the supporting statement and any related forms for the final collections discussed above, please visit CMS's website at *www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this final rule and identify the rule (CMS–9930–F), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due May 17, 2018.

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes standards related to the risk adjustment program for the 2019 benefit year, as well as certain modifications that will promote State flexibility and control over their insurance markets, reduce burden on stakeholders, and protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule and previous Payment Notices provided detail on the implementation of the risk adjustment program, including the specific parameters applicable for the 2014, 2015, 2016, 2017, and 2018 benefit years. This rule finalizes additional standards related to EHBs; cost-sharing parameters; QHP certification; the Exchanges, including terminations, exemptions, eligibility and enrollment; AV for stand-alone dental plans; MEC; the rate review program; the medical loss ratio program; the Small Business Health Options Program; and FFE and SBE–FP user fees.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

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

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule—(1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of $100 million or more in at least 1 year, and therefore, meets the definition of ''significant rule'' under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule.

The provisions in this final rule aim to improve the health and stability of the Exchanges, and to provide States with additional flexibility and control over their insurance markets. They will reduce regulatory burden, and reduce administrative costs for issuers and States, and will lower net premiums for consumers. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage. Although there is some uncertainty regarding the net effect on enrollment and premiums, we anticipate 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; that markets are stable; and that Exchanges operate smoothly.

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 PPACA is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage or government-sponsored coverage. The provisions within this final rule are integral to the goal of expanding coverage. For example, the risk adjustment program helps prevent risk selection and decrease the risk of financial loss that health insurance issuers might otherwise expect in 2019.

HHS anticipates that the provisions of this final rule will help further the Department's goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices, that Exchanges operate smoothly, that the risk adjustment program works as intended, and that States have more control and flexibility over EHBs, QHP certification and the operation and establishment of Exchanges. Affected entities such as QHP issuers will incur costs to comply with the proposed provisions, for example, those related to the functions of a SHOP; including calculating the minimum participation rate at the employer level and processing SHOP enrollments for employers and employees; and States will incur costs if they select a new EHB-benchmark plan under the new regulations. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

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

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

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to 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 any reduction in burden related to changes in the timing related to State deadlines for submission of rate filings from issuers that only offer non-QHPs; increased flexibility for Exchanges related to the removal of certain requirements for Navigator programs and non-Navigator assistance personnel entities; increased access to the direct enrollment pathway stemming from permitting a third-party entity to conduct operational readiness reviews for agents, brokers, and issuers; benefits to Exchanges related to proposed simplifications of verification requirements; benefits to consumers, issuers or Exchanges related to the changes related to the special enrollment periods; increased flexibility for States relating to the proposals regarding the SHOP enrollment process; and potential decreases in premiums to consumers related to removing actuarial value standards for SADPs—and certain costs—such as the costs incurred by small employers, agents and brokers, and potential increases in out-of-pocket costs to consumers related to removing actuarial value standards for SADPs; and costs to issuers, brokers, agents, and employers related to changes in SHOP enrollment procedures. The effects in Table 13 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers. The annualized monetized costs described in Table 13 reflect direct administrative costs to health insurance issuers as a result of the finalized provisions, and include administrative costs associated with States requesting a reduction in risk adjustment transfers for the State's individual, small group or merged market, the reduction in costs relating to issuers and States having to no longer submit rate increases for student health insurance plans to HHS, and costs associated with States seeking an adjustment to the MLR standard in the State's individual market that are estimated in the Collection of Information section of this final rule. The annual monetized transfers described in Table 13 include costs associated with SBE–FP user fees, the risk adjustment user fee paid to HHS by issuers, and reductions in rebate payments from issuers to consumers related to QIA and MLR adjustments. We are finalizing a risk adjustment user fee to collect $1.80 per enrollee per year from risk adjustment issuers to operate the risk adjustment program on behalf of States, which we expect to cost

approximately $40 million, similar to the $40 million in contract costs expected for benefit year 2018 when we established a $1.68 per-enrollee-per-year risk adjustment user fee rate. As in 2018, the risk adjustment user fee contract costs for 2019 include additional costs for risk adjustment data validation; however, we expect reduced costs related to issuer outreach and education as issuers gain familiarity with the risk adjustment program, and lower enrollment in risk adjustment covered QHPs, and additional costs to include administrative and personnel costs related to the risk adjustment program that were inadvertently excluded in prior years' cost estimation, which together results in a slightly higher risk adjustment user fee rate than the benefit year 2018 rate. As we generally expect similar risk adjustment user fee costs as the 2018 benefit year, there are no changes to the risk adjustment user fee transfers to include in Table 13. Also, we expect a decrease in FFE user fee collections necessary as we estimate lower contract costs due to streamlining of FFE operations and an increase in premiums but also lower enrollment, resulting in a proposed user fee rate of 3.5 percent for 2019, which is the same as the FFE user fee rate established for 2014 through 2018 benefit years. However, the decrease in user fee collections required to support FFE functions for the 2019 benefit year will be similar to the updated costs for the 2018 benefit year, and the user fee rate will yield the same amount of transfers from FFE issuers to the Federal government as in the prior benefit year. Therefore, there are no changes to the FFE user fee transfers to include in Table 13. We also proposed an SBE–FP user fee rate to be set at 3.0 percent for benefit year 2019, which is higher than the 2.0 percent SBE–FP user fee rate we finalized for the 2018 benefit year. In this rule, we also finalized a proposal to cease charging user fees on SHOP issuers offering plans through an FFE or SBE–FP starting for plan years beginning on and after January 1, 2018.

TABLE 13—ACCOUNTING TABLE

Benefits:

Qualitative:
- Greater market stability resulting from improvements to the risk adjustment methodology.
- Potential increased enrollment in the individual market stemming from lower premiums, leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.[a]
- More informed Exchange QHP certification decisions.
- Increased coverage options for small businesses and employees with less adverse selection.
- Cost savings to consumers and issuers due to reduced administrative costs for issuers.
- Potential decreases in premiums associated with States opting to select a new EHB-benchmark plan.
- Reduced burden to Exchanges, due to the removal of the requirements that each Exchange must have at least two Navigator entities, and that one of these entities must be a community and consumer-focused nonprofit group, and the removal of the requirement that each Navigator (and each non-Navigator entity subject to § 155.215) maintain a physical presence in the Exchange service area.
- Reduced costs and burden and increased flexibility to agents and brokers performing direct enrollment and their third-party auditors due to the removal of the requirement to obtain HHS approval to perform reviews.
- Reduction in administrative costs to issuers due to the removal of the meaningful difference standard, and final changes to the SHOPs.

Costs:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	−$26.71	2016	7	2018–2022
	−25.54	2016	3	2018–2022

Quantitative:
- Costs incurred by issuers and States to comply with provisions in the final rule as detailed in the Collection of Information Requirements section, taking into account the reduction in burden and costs for issuers and States due to the elimination of the requirement to submit rate reviews to HHS for student health insurance coverage[b] and increase in the rate review threshold and the reduction in burden and costs to States related to the requests for adjustment to the MLR standard in their individual markets.
- Reduction in costs to issuers due to changes to the requirements for risk adjustment data validation.
- Reduction in potential costs to Exchanges since they will no longer be required to conduct sampling as a verification process for eligibility for employer-based insurance starting plan year 2018, and can instead conduct an alternate process through plan year 2019.
- Costs incurred by Exchanges to implement new verification requirements for income inconsistencies.
- Regulatory familiarization costs.

Qualitative:
- Costs due to increases in providing medical services (if health insurance enrollment increases).
- Costs to issuers of redesigning SADPs to account for the removal of actuarial value standards for SADPs.
- Potential increases in out of pocket costs associated with States opting to select a new EHB-benchmark plan.
- Potential increases in out of pocket costs and loss of benefits and services associated with substitution between EHB categories.[c]
- Potential increase in consumer burden related to plan comparisons in those States allowing substitution between EHB categories.

Transfers:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized ($/year)	$17.8	2017	7	2018–2022
	18.6	2017	3	2018–2022
Other Annualized Monetized ($/year)	87	2017	7	2018–2022
	87	2017	3	2018–2022

Costs:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Quantitative:				
• Transfer from health insurance issuers to the Federal government of $40 million as risk adjustment user fees for 2022 (the same amount as previously estimated for 2018–2021).				
• Increased transfers from SBE–FP issuers to the Federal government of $20 million due to increase in user fee rate from 2.0 set in 2018 to 3.0 percent final for 2019.				
• Decrease in user fee transfers from SHOP issuers offering plans through an FF–SHOP or SBE–FP for SHOP to the Federal government of approximately $6 million in 2019.				
• Reduced transfers to consumers from health insurance issuers in the form of rebates of $75 million to $87 million due to final amendments to the medical loss ratio requirements.[d]				
Qualitative:				
• Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling.				
• A decrease in the premiums and risk adjustment transfers in the individual, small group or merged markets as a result of potential State requests to reduce risk adjustment transfers for the State's individual, small group or merged market.				
• Potential increases in premiums associated with adjustments to MLR.				
• Potential decreases in premiums associated with removal of AV standards for SADPs.				
• Potential increases in out of pocket costs associated with removal of AV standards for SADPs.				

[a] Removal of AV standards for SADPs may reduce enrollment due to reductions in coverage and potential higher out-of-pocket costs.
[b] The reduction in burden and costs associated with student health insurance could result in lower premiums.
[c] Some consumers may experience an increase in services and benefits. The net result is uncertain.
[d] For the purpose of calculating total transfers, the upper bound was used.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the PPACA's impact on Federal spending, revenue collection, and insurance enrollment. The PPACA transitional reinsurance program and temporary risk corridors program end after the benefit year 2016. Therefore, the costs associated with those programs are not included in Tables 14 or 15 for fiscal years 2019–2022. Table 14 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2018 through 2022, 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 14. We note that transfers associated with the risk adjustment program 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 13).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions proposed in this rule are consistent with our previous estimates in the 2018 Payment Notice for the impacts associated with the APTC, the premium stabilization programs, and FFE user fee requirements.

TABLE 14—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FISCAL YEAR 2018–2022

[In billions of dollars]

Year	2018	2019	2020	2021	2022	2018–2022
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	5	5	5	6	6	27
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections*	5	5	6	6	6	28

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 $1 million in payments in FY 2018 that are collected in prior fiscal years. CBO does not expect a shortfall in these programs.
Source: Congressional Budget Office. *Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2017 to 2027* Table 2. September 2017. Available at *https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53091-fshic.pdf*.

1. Risk Adjustment

The risk adjustment program is a permanent program created by the PPACA that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. We established standards for the administration of the risk adjustment program, in subparts D and G of part 153 in Title 45 of the CFR.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014 through 2018 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 2019 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2019 will be approximately $40 million, and that the risk adjustment user fee would be approximately $1.80 per enrollee per year. This user fee reflects costs to support the risk adjustment data validation process in 2019, lower costs related to risk adjustment issuer outreach and education and lower enrollment in risk adjustment covered QHPs, and includes administrative and personnel cost related to the risk adjustment program, resulting in a slightly higher user fee rate for 2019 than the 2018 benefit year rate.

We believe that the approach of blending the coefficients calculated from the 2016 benefit year enrollee-level EDGE data with 2014 and 2015 MarketScan® data finalized in this rule will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2018 benefit year to the 2019 benefit

year due to differences in the datasets' underlying populations.

We are finalizing the provision for States to request a reduction in risk adjustment transfers in the individual, small group or merged market. We expect this policy will reduce transfers proportional to the percent by which the States seek to reduce the transfers to account for State-specific market rules or relevant factors without the necessity for States to undertake operation of their own risk adjustment program. However, because the risk adjustment program is budget neutral, any State decision to request a reduction in the risk adjustment transfers will have no net impact on risk adjustment transfers.

2. Risk Adjustment Data Validation

We are finalizing several changes to the requirements for risk adjustment data validation that overall would reduce regulatory burden and costs for issuers of risk adjustment covered plans. HHS believes that adjusting issuers' risk adjustment risk scores only when an issuer's failure rate for a group of HCCs is statistically different from the weighted mean failure rate for that group of HCCs for all issuers that submitted initial validation audits will help market stability by increasing issuers' ability to predict risk adjustment transfers and liquidity needs. We anticipate that many issuers required to participate in risk adjustment data validation will not have their risk scores adjusted, based on our analysis of error rates in the Medicare risk adjustment data validation program.

We anticipate that the post-transfer adjustment of risk adjustment transfers for issuers that exited a State market will result in transfer adjustments for a small subset of issuers that previously would not have had their transfers adjusted, but HHS does not expect this policy to increase burden for these issuers, especially in light of the revised payment adjustments for error rates policy finalized in this rule.

HHS estimates that not requiring issuers that have 500 or fewer billable member months Statewide to conduct an initial validation audit beginning in the 2017 benefit year will reduce the administrative burden and costs on those issuers. The reduction in burden and costs related to this ICR has been discussed previously in the Collection of Information Requirements section.

Under the change to the sampling methodology finalized in this rule, issuers that were the sole issuer in a risk pool will still need to provide a sample for data validation, but the sample will not include enrollees from the risk pool where they were the sole issuer. Therefore, this change will not have a significant impact on costs or burden for affected issuers.

We are finalizing an amendment to § 153.630(b)(6) to state that a qualified provider licensed to diagnose mental illness that is prohibited by State privacy laws from furnishing a complete medical record for data validation may furnish a signed mental or behavioral health assessment that providers routinely prepare along with the required attestation. For risk adjustment data validation purposes, a mental or behavioral health assessment should, to the extent permissible under applicable State and Federal privacy laws, contain: (i) The enrollee's name; (ii) sex; (iii) date of birth; (iv) current status of all mental or behavioral health diagnoses; and (v) dates of service. The burden associated with this requirement has been discussed previously in the Collection of Information Requirements section.

We are finalizing an amendment to § 153.630(b)(9) to state that, if an issuer of a risk adjustment covered plan (1) fails to engage an initial validation auditor; (2) fails to submit the results of an initial validation audit to HHS; (3) engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or (4) intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS, HHS may impose CMPs in accordance with the procedures set forth in § 156.805(b) through (e). Because risk adjustment data validation has thus far operated as a pilot program, we cannot estimate the number of issuers that will be subject to CMPs. However, we do not expect that a significant number of issuers will engage in the extreme misconduct required to warrant a CMP under this amended regulation.

3. Rate Review

We are amending § 154.103 to exclude student health insurance coverage effective on or after July 1, 2018 from the Federal rate review requirements. This will reduce burden related to rate review submission and review for issuers and States. In addition, providing States with more flexibility regarding timing of submission of rate filing justification from issuers that offer non-QHPs only, and reducing the advance notification requirement for rate increase announcements, will reduce regulatory burden for issuers and States. The reduction in burden and costs related to ICRs have been discussed previously in the Collection of Information Requirements section.

Raising the Federal default review threshold from 10 percent to 15 percent will reduce administrative burden for issuers and States while continuing to provide the Secretary and the States with the information necessary to effectively carry out their responsibilities to monitor rate increases inside and outside of Exchanges. As discussed previously in the Collection of Information Requirements section, issuer burden will decrease by an estimated $20,576 and the State burden will decrease by an estimated $519,674 annually. Given that only one rate filing subject to review over the last 4 years in the 10 to 15 percent rate increase range was determined to be unreasonable, we feel this is a reasonable tradeoff for the potential burden savings.

4. Additional Required Benefits (§ 155.170)

We are extending the applicability of the policies governing State-required benefits at § 155.170 to the policies finalized at § 156.111, which provide States with new options for selecting their EHB-benchmark plans beginning for the 2019 plan year. Specifically, under any of the three EHB-benchmark plan selection options, or if the State defaults to its current EHB-benchmark plan, the policies regarding State-required benefits will continue to apply. Because these policies continue to be in effect, we do not anticipate any additional burden on States or issuers.

5. Standards for Navigators and Certain Non-Navigator Assistance Personnel (§§ 155.210 and 155.215)

We amended § 155.210(c)(2) to remove the requirements that each Exchange must have at least two Navigator entities and that one of these entities must be a community and consumer-focused nonprofit group. We also amended §§ 155.210(e)(7) and 155.215(h) to remove the requirements that Navigators and non-Navigator assistance personnel entities subject to those regulations maintain a physical presence in the Exchange service area. These amendments to § 155.210(c)(2) will reduce the burden on Exchanges to have at least two separate Navigator entities, and as a result, Exchanges may be able to reduce funding amounts while still meeting program requirements. Removing these requirements will help promote flexibility and autonomy for each Exchange to structure its Navigator program, and to award grant funding to the number and type of entities that will be most effective and efficient for that specific Exchange service area. To the

extent that Exchanges take advantage of these flexibilities, consumers may have fewer options of Navigator grantees and may not have access to a Navigator grantee or a non-Navigator assistance personnel entity that maintains a physical presence in the Exchange service area. Exchanges continue to have the flexibility to fund more than one Navigator grantee and State Exchanges continue to have the flexibility to require that Navigators maintain a physical presence in the Exchange service area.

6. Standards for Third-Party Entities To Perform Audits of Agents, Brokers, and Issuers Participating in Direct Enrollment (§ 155.221)

The final regulations replace the requirement that an HHS-approved third party perform audits of agents and brokers participating in direct enrollment and use their own internet website for QHP selection or to complete the Exchange eligibility application to instead permit an agent, broker or issuer to select a third-party entity that meets HHS requirements to conduct an annual operational readiness review prior to participating in direct enrollment. HHS anticipates this approach will reduce the regulatory burden on agents, brokers, and issuers participating in direct enrollment. HHS also anticipates these changes will reduce the burden on third-party auditors performing reviews under § 155.221, as those entities will no longer be required to obtain HHS approval to perform the reviews. Furthermore, we believe this policy will expand the available number of qualified third-party auditors by removing any time and operational restrictions imposed by the HHS pre-approval requirement, which will provide more flexibility to agents, brokers, or issuers as they complete operational readiness reviews. Additionally, we believe this will enable more agents, brokers and issuers to demonstrate operational readiness by reducing the burden on HHS for conducting reviews, expediting the ability of these entities to demonstrate readiness, and increasing the feasibility of approval for use of innovative pathways, thereby creating more opportunities for enrollment in QHP coverage for consumers, potentially increasing enrollment. HHS anticipates that some of the burden will be lessened by the fact that many agents, brokers, or issuers already have the established privacy and security controls, and may have existing relationships with auditors that could be leveraged for these reviews. We intend to provide additional technical details regarding compliance with the specific requirements under these rules in guidance in the future.

7. Eligibility Standards (§ 155.305)

The requirement in § 155.305(f)(4)(ii) that the Exchange must send direct notification to the tax filer before denying eligibility for APTC to consumers who fail to file and reconcile went into effect in mid-January 2017; therefore, it did not impact operations for the 2017 open enrollment period, which was nearly over then. At that point in time, for the FFE, the household contacts for non-filers had been notified of their tax filer's non-compliance, and APTC had been discontinued at auto re-enrollment for those who did not file a Federal income tax return according to IRS data or inform the FFE that they had filed a Federal tax return and reconciled past APTC. Requiring the Exchange to deny APTC for failure to file and reconcile even in the absence of ''direct notification . . . to the tax filer'' is unlikely to add new burden since Exchanges have not yet implemented § 155.305(f)(4)(ii). We do not believe that Exchanges have built an FTI-compliant noticing infrastructure since the publication of the final rule establishing § 155.305(f)(4)(ii) that they will need to dismantle. However, removing § 155.305(f)(4)(ii) avoids significant costs for Exchanges that, as discussed above, no longer must build the infrastructure necessary to directly notify tax filers about their tax filing status while protecting FTI.

8. Verification Requirements (155.320)

This rule amends § 155.320(c)(3)(iii) to create annual income data matching issues when applicants attest to income above 100 percent FPL, but trusted data sources show income below 100 percent FPL. We estimate that each SBE will incur one-time costs of approximately $450,000 to complete the necessary system changes to implement this policy. For 12 SBEs, the estimated total cost will be $5.4 million. This estimate does not take into account the ongoing operational expenses of processing data matching issues from this new requirement. Ongoing operational costs will be dependent on the Exchange's number of applicants with income inconsistencies and the threshold for setting a data matching issue.

This final rule will amend § 155.320(d)(4) to allow an Exchange to conduct an HHS-approved alternative process instead of sampling, as provided under paragraph (d)(4)(ii) through benefit year 2019. We believe this will relieve Exchanges from the burden of investing resources to conduct sampling when the FFEs' study of a sampling-like process found that this method of verification may not be cost-effective for some Exchanges at this time. We estimate the burden associated with sampling based in part on the alternative process used for the FFEs. HHS incurred approximately $750,000 in costs to design and operationalize this study and the study indicated that $353,581 of APTC was potentially incorrectly granted to individuals who inaccurately attested to their eligibility for or enrollment in a qualifying eligible employer-sponsored plan. We placed calls to employers to verify 15,125 cases but were only able to verify 1,948 cases. A large number of employers either could not be reached or were unable to verify a consumer's information, resulting in a verification rate of approximately 13 percent. The sample-size involved in the 2016 study did not represent a statistically significant sample of the target population and did not fulfill all regulatory requirements for sampling under paragraph (d)(4)(i) of § 155.320.

Taking additional costs into account—namely, the cost of sending notices to employees as required under paragraph (d)(4)(i)(A), the cost of building the infrastructure and implementing the first year of operationalizing this process, and the cost of expanding the number of cases to a statistically significant sample size of approximately 1 million cases—we estimate that the overall cost of implementing sampling would be approximately $8 million for the FFE, and between $2 million and $7 million for other Exchanges, depending on their enrollment volume and existing infrastructure. Therefore, we estimate that the average per-Exchange cost of implementing sampling that resembles the FFE's approach would be approximately $4.5 million for a total cost to SBEs of $54 million, when assuming 12 SBEs (operating in 11 States and the District of Columbia). This cost estimate does not, however, take into account the cost of notifying consumers when the information provided by their employer changes their eligibility determination described under paragraph (d)(4)(i)(E), the cost of providing employees consumer support that may be needed to understand notices and any change in eligibility, or the cost of ending those consumers' APTCs, when necessary. This estimate also does not account for the unique operating costs of each Exchange, the change to paragraph (d)(4) to allow

Exchanges to continue to use an alternate process through benefit year 2019, and the flexibility afforded Exchanges described at § 155.315(h) and referenced in § 155.320(a)(2).

We believe this finalized change will lessen the financial and technical burdens on Exchanges under current regulation and allow Exchanges to conduct an alternative process to sampling under paragraph (d)(4) as approaches to sampling are refined and data bases are compiled over time. We sought comment on the reduction in burden associated with extending the option to allow Exchanges to fulfill verification requirements by conducting an HHS-approved alternative process to sampling through plan year 2019. We did not receive any comments on the reduction of burden associated with our proposed change.

9. Special Enrollment Periods (§ 155.420)

We do not anticipate that the revisions to § 155.420 will create significant costs or burdens because several changes will simplify special enrollment period policy, and we also believe that they will generate some benefit in the form of added efficiency for Exchanges and improvements in some consumers' ability to maintain continuous coverage and understand their coverage options.

For example, the amendment to paragraph (d)(1)(iii) allows Exchanges to provide similar treatment to all women losing non-MEC pregnancy-related coverage, which enables a more streamlined special enrollment period eligibility process.

Additionally, the revisions in paragraph (b)(2)(i) align regulatory policy for special enrollment periods based on a court order with other similar special enrollment period types, and create operational efficiencies for Exchanges by streamlining effective date options across similar special enrollment periods with qualifying events related to gaining or becoming a dependent. For example, this revision to the regulation will enable the FFE to use a simpler online, automated application pathway for more special enrollment period-eligible consumers, meaning that fewer consumers will need to use a manual and costly casework process to use their special enrollment period. For limited cases when casework support is required, operations would also be simplified.

We acknowledge that this may not be the case for all Exchanges, and that an Exchange that has automated the option for consumers to elect that their coverage take effect on the first of the month after the date of their qualifying event may need to make updates so that consumers instead have the option to elect that their coverage take effect the first of the month after their date of plan selection. However, as discussed in the preamble, we believe that this burden will be limited, and mitigated due to the fact that offering a ''first of the month'' coverage effective date is optional for Exchanges, permitting a delayed rollout if necessary.

Additionally, amending paragraph (a)(5) to exempt qualified individuals from the prior coverage requirement that applies to certain special enrollment periods if they lived in a service area where no qualified health plan was available through the Exchange for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420, may provide a pathway to coverage for a small group of individuals, and is not anticipated to impact the Exchange risk pool. It may generate burden on Exchanges due to required technical and operational updates should it become necessary to implement, but we anticipate that this burden will be mitigated by the small size of the affected group and by practices that are already in place in many Exchanges to verify eligibility for special enrollment periods. Additionally, Exchanges already exempt qualified individuals from the prior coverage requirement who may not previously have had access to QHP coverage through an Exchange, including those who were previously living in a foreign country or United States territory and Indians as defined by section 4 of the Indian Health Care Improvement Act. Therefore, we do not believe that adding an additional small population to this exemption will create additional costs or burdens.

Finally, because simplified special enrollment period eligibility policy provides improved pathways to continuous coverage for special enrollment period-eligible consumers, we anticipate that the provisions in this rule may result in less burden on call center representatives and caseworkers related to fewer questions about special enrollment periods due to gaining or becoming a dependent and loss of certain types of pregnancy-related coverage. We also anticipate that the revisions will reduce burden on consumers, have a positive effect on the risk pool, and not result in additional costs or burdens for issuers.

In addition, some States that operate Exchanges expressed concern that amending the plan option restrictions available to dependents who are newly enrolling in a plan with a QHP enrollee through a special enrollment period will increase the burden on States, which will be required to do a system build to align their systems with this change. We appreciate these concerns raised by States, but do not anticipate that this change will add significant additional burden on top of the system builds States are already doing. The intent of this policy change is to streamline the plan option rules for dependents who are newly enrolling in coverage with enrollees through a special enrollment period and so we anticipate that any additional burden incurred to amend Exchange system functionality will be offset by the efficiencies gained in streamlining Exchange eligibility rules.

10. Effective Dates for Terminations (§ 155.430)

Permitting all enrollee-initiated terminations to become effective on the date of enrollee request or a later date of their choosing, and removing the special termination effective date for newly eligible Medicaid/CHIP/BHP consumers streamlines termination effective dates for Exchanges and reduces complication and confusion among consumers and issuers. Exchanges and issuers were not expected to incur new costs by aligning these termination dates, as Exchanges and issuers are well acquainted with same-day termination transactions. However, we received comments from some SBEs that their systems would not allow for mid-month terminations. Therefore, we are not requiring the alignment of termination effective dates as proposed, but rather are providing Exchanges flexibility to choose whether to implement the changes that were proposed. Operationalizing the aligned termination dates may reduce system errors and related casework, as well as confusion for consumers, issuers, and caseworker and call center staff based on contradictory rules for different scenarios.

11. Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the amendment to § 155.605(d) will create additional costs or burdens. The amendment to § 155.605(d)(2)(iv) will enable the Exchanges to process the consumer's exemption from the individual shared responsibility provision due to lack of affordable coverage based on projected income, for those not eligible for employer-sponsored coverage, when there is no bronze plan available by allowing the Exchanges to process the consumer's

exemption based on the lowest cost Exchange metal level plan, excluding catastrophic coverage, available in the individual market through the Exchange in the State in the county in which the individual resides. This policy will not increase the burden on consumers or Exchanges. Without these revisions, individuals may lack access to qualifying or affordable health coverage, but be unable to qualify for an exemption from the individual shared responsibility provision to purchase qualifying health coverage and the associated financial penalty due to the lack of coverage in their area or the inability to calculate whether coverage is unaffordable. This policy will also not result in additional costs or burdens for issuers.

12. Small Business Health Options Program (Part 155, Subpart H, § 155.200, §§ 156.285 and 156.286, § 156.350, §§ 157.205 and 157.206)

HHS is finalizing the proposal to grant additional flexibilities, for plan years beginning on or after January 1, 2018, to small employers enrolling in SHOP QHPs and to participating QHP issuers in how they interact with a SHOP. These changes will be effective as of the effective date of the final rule and the FF–SHOPs and SBE–FPs for SHOP will operate under the new enrollment approach. Under this final rule, several existing requirements on SHOPs will not apply for plan years beginning on or after January 1, 2018, allowing State Exchanges the flexibility to operate their SHOP in a way that makes sense for the small businesses in their State, with reduced limitations imposed by Federal regulation. The FF–SHOPs and SBE–FPs for SHOP will take advantage of the flexibility of the enrollment approach described through this final rule and operate in a leaner fashion. Under the approach being finalized, SHOPs are no longer required to enroll small groups in SHOP QHPs through a SHOP website. Instead, small employers will, in SHOPs that operate under this approach, enroll through a participating QHP issuer, or a SHOP-registered agent or broker.

HHS believes that the changes will reduce burden on participating QHP issuers, small employers, and agents and brokers for several reasons. Under the approach being finalized, for plan years beginning on or after January 1, 2018, effective on the effective date of this rule, participating QHP issuers will, in SHOPs that operate under the new flexibilities like the FF–SHOPs and SBE–FPs for SHOP, enroll small groups through their existing enrollment channels—utilizing their existing technologies and processes. Small groups enrolled in SHOP QHPs for plan years before January 1, 2018 will not be affected by the proposed changes to enrollment through a SHOP until they are due to renew in a SHOP QHP for the 2018 plan year. While some additional requirements will be imposed onto issuers, HHS anticipates that any additional burden on issuers as a result of the changes in this rule will be negated in an ultimate net reduction in burden as many Federal regulations are being removed and any additional requirements onto issuers mainly consist of practices they currently perform in the private market.

In the 2018 Payment Notice, HHS finalized the removal of a participation provision that had required certain QHP issuers to participate in an FF–SHOP in order to participate in an FFE. As a result, there has been a significant decrease in the number of issuers in the FF–SHOPs in the 2018 plan year and therefore, HHS also expects fewer enrollments in the FF–SHOPs for plan year 2018. As of January 1, 2017, approximately 7,554 employer groups were enrolled in the FF–SHOPs, covering 38,749 lives. With the anticipated significant decreases in QHP issuer participation for enrollment beginning in 2018, it is not cost effective for the Federal government to continue to maintain certain FF–SHOP functionalities, collect significantly reduced user fees on a monthly basis, maintain the technologies required to maintain an FF–SHOP website and payment platform, generate enrollment and payment transaction files, and perform enrollment reconciliation.

Under the approach being finalized in this rule, issuers will still be subject to their State requirements, and HHS will minimize Federal requirements related to SHOP plans (that is, notice requirements, etc.) for plan years beginning on or after January 1, 2018. For example, issuers are often required by State law to generate enrollment and payment notices, and will continue to generate any State-required notices under the new SHOP enrollment approach. Under the proposed approach, the FF–SHOPs and SBE–FPs for SHOP will no longer generate enrollment notices, but the notice requirements for the FF–SHOPs and SBE–FPs for SHOP will not necessarily be transferred directly to participating QHP issuers. HHS can imagine a scenario where an issuer might generate an additional notice to a SHOP consumer that they are not required by Federal law to send, but may be required by State law, to send.

Issuers will still be required to accept enrollment from employers that offer their employees a choice of plans. HHS can foresee a circumstance where an employer offers its employees a choice of plans, across plan categories, and where the employees choose to enroll in plans offered by multiple issuers. In this circumstance, it will also be possible that an issuer will receive one application for enrollment from a group. Under the approach to SHOP enrollment being finalized, the issuer will be required to accept that single enrollment so long as the employer's group has met the minimum participation rate for their State, or is enrolling between November 15 and December 15, when the minimum participation rate rules do not apply. With the decrease in issuer participation in the SHOPs beginning in plan year 2018, HHS believes that a circumstance, similar to the one discussed above may occur. In the absence of premium aggregation functions, issuers, under the approach being finalized will be working directly with an employer, or their appointed SHOP-registered agent or broker for matters of enrollment and premium billing and payment. Under the new regulations, effective as of the effective date of this rule, issuers will be required to enroll consumers into plans, even if only one employee of a group wants to enroll. Further, issuers will also be required to process enrollments into SHOP QHPs, and, handle appeals (other than appeals related to employer eligibility), administer special enrollment periods and terminations. Issuers will still be subject to the market wide effective dates outlined in § 147.104(b)(1)(i)(C). While HHS believes that issuers currently perform the majority of these tasks, issuers may experience an increase in burden as it relates to the volume of consumers enrolling in their SHOP QHPs. Overall, HHS believes that under this approach, issuers will see a net cost savings, as their business processes for SHOP enrollments may be more closely aligned with their current business practices for enrollments outside the SHOP, and they will no longer be remitting user fees for FF–SHOP and SBE–FP SHOP enrollments.

As noted, SHOPs will be given the flexibility to adopt an enrollment approach through which enrollments occur directly with issuers or SHOP-registered agents or brokers, to continue to operate with the same functionalities as they currently do or to develop new practices as permitted by the proposals in this rule. In any case, SHOPs will need to meet only the regulatory minimums outlined in this final rule, therefore minimizing the overall amount

of regulatory requirements that SHOPs will otherwise need to meet. HHS believes that the new flexibility for SHOPs will result in an overall reduction in burden and cost for States operating their own SHOPs because we are providing States with the flexibility to pursue the enrollment approach that best meets their needs, because we are reducing the overall regulatory requirements for the SHOP Exchanges, and for the same reasons described above regarding why the enrollment approach being finalized will reduce burdens on the FF–SHOP and its stakeholders.

Under the new enrollment approach for SHOP plan years beginning on or after January 1, 2018, HHS believes that employers seeking to purchase coverage through an FF–SHOP or SBE–FP for SHOP will experience a reduction in regulatory burden related to enrollment, despite the fact that they may be required to visit at least two websites (the SHOP website and the issuer's website) prior to completing an enrollment in SHOP coverage as they will be able to enroll in coverage through a SHOP-registered agent or broker or through a participating QHP issuer—using issuers' streamlined enrollment technologies. Employers will also be required, as described throughout this document to notify their QHP issuer of their eligibility to purchase a SHOP QHP and of their ineligibility, if their eligibility were to be revoked. Employers will also be required to inform the SHOP if they become ineligible to participate in a SHOP, or choose to withdraw their eligibility, unless the issuer is notified by the SHOP. We believe this is still less cumbersome than the existing eligibility and enrollment process.

Under the flexibilities being finalized with this rule, some employers, specifically those who offer their employees a choice of plans, will experience an increase in administrative burden with the removal of a SHOP's premium aggregation functions. Without a SHOP's premium aggregation functions, employers will have to collect the enrollment and payment information needed from each of the issuers whose plans the employer intends to offer to its employees. In the event employees select plans from multiple insurance companies, the employer will be responsible for distributing the applications for enrollment to the individual issuers, collecting payments from the employees and sending the individual payments to each issuer. Due to the decrease in issuer participation in the FF–SHOPs, some SHOP employers only have one issuer offering FF–SHOP plans in their area and will not be able to offer their employees a choice of plans across issuers. In addition, historically, a majority of employers have not offered employee choice across different issuers. Therefore HHS does not believe the potential increased burden in this area due the removal of premium aggregation functions to be significant. Employers will still be able to view a listing of all of the SHOP QHPs available, by plan category and issuer on a SHOP website. HHS expects that the actual process of enrolling in SHOP QHPs under this approach will be less burdensome than the existing enrollment approach through a SHOP website. As previously mentioned, HHS anticipated significantly lower issuer participation for the SHOP in the 2018 plan year. A decrease in issuer participation unfortunately also results in less choice for consumers. While employers may experience an increase in burden, especially if offering employees a choice of plans, under the new flexibilities for SHOPs, HHS anticipates the benefits of the finalized approach will ultimately outweigh the minimal additional costs employers could face.

Further, the Federal government will experience a dramatic reduction in the role it plays in operating an FF–SHOP and the contract support that it requires in order to support it. In 2016, the cost of running the FF–SHOP website (utilized by both FF–SHOPs and SBE–FPs for SHOP) was approximately $30 million, and HHS expects annual expenditures to drop significantly—by at least 90 percent—within a few years, as it responsibly wind-downs the integration of the FF–SHOPs.

13. User Fees (§ 156.50)

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. In this final rule, for the 2019 benefit year, we set the monthly FFE user fee rate at 3.5 percent of the monthly premium, and the monthly SBE–FP user fee rate at 3.0 percent of the monthly premium. This increase in SBE–FP user fee rate from 2.0 percent in 2018 to 3.0 percent in 2019 will increase transfers from SBE–FP issuers to the Federal government by $20 million. Additionally, we will cease charging monthly user fees to SHOP issuers offering plans through an FF–SHOP or SBE–FP SHOP for plan years beginning on and after January 1, 2018, effective on the effective date of the final rule. This will decrease user fee transfers from SHOP issuers offering plans through an FFE or SBE–FP by approximately $6 million.

14. Provision of EHB

Under § 156.111, we provide States with more flexibility by offering States three new methods for selecting their State EHB-benchmark plans. Under this policy, if the State does not select one of the three methods for changing its EHB-benchmark plan, the State will default to its current EHB-benchmark plan. We recognize that, to the extent that States take advantage of the EHB-benchmark plan selection options at § 156.111, States and issuers will experience an increase in burden to develop new policies and implement new plan designs. We anticipate that most States will need to invest resources to analyze the three new EHB-benchmark selection options to make an informed selection, even if the State ultimately defaults. Several States may select one of the new options, and will need additional resources to facilitate a public notice and comment period and develop and submit the necessary documents specified by HHS (including the requisite actuarial certification) to effectuate the State's selection. Additionally, in States that choose to select their EHB-benchmark plan under any of the three available options, issuers offering plans that provide EHB will incur additional administrative costs associated with designing plans compliant with the State's newly selected EHB-benchmark plan.

Due to the many PPACA policies directly or indirectly tied to EHB, HHS recognizes the impact this policy will have on parties beyond issuers required to provide EHB-compliant plans. For example, the State's new EHB-benchmark selection can impact how issuers set their annual limitation on cost sharing and how issuers determine which benefits may not be subject to annual and lifetime dollar limits.[104]

It is our aim that the flexibility under the policy will allow for States and issuers to be more innovative in designing benefit structures that will ultimately affect affordability for consumers. However, we realize that

[104] The definition of EHB also has an impact on the annual limitation on cost sharing at section 1302(c) of the PPACA (which is incorporated into section 2707(b) of the PHS Act) and the prohibition of annual and lifetime dollar limits at section 2711 of the PHS Act, as added by the PPACA.

this policy will have varying impact on consumers depending on how a State chooses to implement the policy. Consumers enrolled in individual and small group market plans will be affected by changes to EHB in that their benefits may change and in some cases premiums may increase or decrease depending upon State implementation of the policies. Additionally, in States that use one of the methods to select a new EHB-benchmark plan, the new EHB-benchmark plan selection may impact the amount of PTC and CSRs for enrollees in the State. For these consumers, subsidies will increase or decrease when compared to their State's current EHB-benchmark plan. PTC is available only for that portion of a plan's premium attributed to EHB. To the extent that a State's EHB-benchmark plan, under the policy, leads to lower premiums for the second lowest cost silver plan, PTC will be reduced, but not the percent of income a consumer with PTC is expected to contribute to their premium. This effect will represent a transfer from consumers who receive PTC to the Federal government. Individual and small group market enrollees who do not receive PTC will experience lower premiums for less comprehensive coverage that can result in more affordable coverage options but possibly higher out-of-pocket costs for the consumer.

We anticipate that States are more likely to select EHB-benchmark plans under this policy such that premiums have the potential to be reduced in the long-term to achieve affordability in benefit design. However, even with the generosity standard now being applied to all of the EHB-benchmark selection options, the policy may provide some ability for States, depending on the State, to select EHB-benchmark plans in a manner that will increase premiums. To the extent that a State's EHB-benchmark plan leads to higher premiums for the second lowest cost silver plan, PTC will be increased.

Consumers who have specific health needs may also be affected by the policy. In the individual and small group markets, depending on the selection made by the State in which the consumer lives, consumers with less comprehensive plans may no longer have coverage for certain services. In other States, again depending on State choices, consumers may gain coverage for some services.

As explained above, HHS anticipates that § 156.111 will generate additional costs for States, issuers, and certain consumers in the short run. However, although we are uncertain as to how States will take advantage of this flexibility, and States are not required to make any changes under this policy, we also believe the additional flexibility in plan and benefit design may produce long-term premium savings. The policies offer issuers in States that use the flexibility to select a new EHB-benchmark plan the opportunity to lower plan premiums, which will increase affordability of health insurance for consumers in the individual and small group markets who do not receive PTC and do not require the benefits that are no longer considered EHB.

When adjusting coverage of services under the options, we encourage States to consider the spillover effects in addition to the costs and utilization of these services. Spillover effects include increased use of other services, such as increased use of emergency services or increased use of public services provided by the State or other government entities, when a certain service is no longer covered by insurance. Depending on the State population's use of services and health care needs, States may arrive at different conclusions about the effects of adjusting a particular benefit. Because we do not know how States will choose to adjust their benchmark plans, we are not able to predict the effects these modifications may have on costs.

Additionally, we also proposed at § 156.115 to allow for benefit substitution to occur within the same EHB category or between EHB categories to offer additional issuer flexibility. Because issuers are already familiar with substituting benefits within benefit categories, we did not believe that broadening the policy to allow benefit substitution between benefit categories would create additional burden for issuers. We are finalizing § 156.115 to allow issuers to substitute benefits between EHB categories to the extent allowed by the State, beginning in plan year 2020. As finalized, this rule will increase burden on consumers, when their State allows between-category substitution and issuers in their State utilize such substitution. Under such circumstances, consumers who choose between plans offered in the individual and small group markets may need to spend more time and effort comparing benefits offered by different plans in order to determine what, if any, benefits are substituted, and what plan would best suit their health care and financial needs. However, some consumers may benefit from expanded access to plans that better suit their needs. We also note that States are generally primarily responsible for enforcement of EHB and continue to have the option to set criteria for benefit substitution.

We solicited comments on the impact of the proposed EHB policy and on whether other impacts should be considered.

Comment: Many commenters were concerned about the impact of the proposed EHB-benchmark plan policies. Some commenters were concerned that reduced benefits might lead to consumers forgoing care, which could lead to a more serious condition that would increase or shift costs. Some commenters focused on the potential downstream effects, with most commenters agreeing with our assessment that there may be potential downstream effects that a State would want to take under consideration, with some noting that the spillover could also affect the productivity of the nation, leading to even higher government costs.

Commenters on the premium impact and cost impact of the proposed policy typically were concerned that reducing benefits would only have a minor or no premium impact and would result in consumers having to pay more for services that are not covered, which some noted is not what consumers want. Some of these commenters noted that premiums are affected by other factors than benefits while some commenters were concerned about the risk pool impact and risk adjustment since enrollment could be affected by the scope of benefits being offered. Other commenters noted that Medicaid, the large group and self-insured plans, and PTC are also affected by the definition of EHB.

Commenters also opposed allowing issuers to substitute benefits between EHB categories. Commenters cited a wide range of concerns, including those we acknowledged in the proposed rule, as well as several that we did not, and suggested that the proposal's negative impact would be significant. For example, commenters noted that this type of substitution would permit issuers to design plans so that they were unattractive to people with certain high-cost health conditions, or people with conditions not adequately reimbursed by risk adjustment. They voiced concerns that this new market dynamic could harm the individual market risk pool and State risk adjustment programs, as well as imposing burden on certain individuals with chronic or high cost conditions affected by the lack of coverage options that met their needs and the difficulty of comparing plans due to the increased complexity of plan design.

Commenters also stated that substitution between EHB benefit categories is significantly different than substitution within categories and, therefore that current substitution practices do not provide helpful precedent for plan design, or for States' review of plans that include substitution within categories. One commenter stated that it would be particularly difficult to establish actuarial equivalence between benefits from different EHB-benefit categories, which could result in added burden for State regulators and for issuers required to comply with varying standards in different States. One commenter added that while this proposal would allow States to bar issuers from using benefit substitution between EHB categories, some States would need to take this step through legislative action, which would require time and resources simply to maintain their current policy. Finally, we did not receive any examples of how issuers could use substitution between EHB benefit categories to improve coverage options.

Response: In response to commenters, we are finalizing the new EHB-benchmark plan options at § 156.111 with certain modifications. Because we do not know how States will choose to adjust their benchmark plans, we are not able to predict the effects these modifications may have on costs. Furthermore, we also recognize that the effects of a specific change will likely vary from State to State given market and demographic differences. Therefore, we emphasize that States may also wish to consider a variety of different factors when selecting an EHB-benchmark plan. We encourage States to consider the impact of the EHB-benchmark plan's scope of benefits on the availability of PTC and CSRs for enrollees in the State, as the PTC is based on the amount of premiums allocable to EHB, and CSRs provide reduced cost sharing for EHB only. Additionally, we encourage States to consider the impact on Medicaid, and on large group and self-insured group health plans. While we cannot predict the effects of the policy, we hope that this policy, as finalized, allows States the flexibility to innovate their EHB-benchmark plans that balances access and costs. We hope to learn from those States that choose a new EHB-benchmark plan under this policy, as we consider creating a Federal default benchmark plan in the future.

We appreciate commenters' concerns about the impact of allowing substitution between EHB categories. We assess the impact on States to be minimal, as under the final rule they have authority to withhold permission for substitution between categories. We also expect minimal impact on issuers, since they have experience in substituting benefits within EHB categories and may decline to substitute between categories even when their State allows it.

We anticipate both additional burden and benefit for consumers, to the extent that their States permit and issuers utilize substitution between EHB categories. It may require greater time and effort for consumers to choose among plans in the individual and small group market if some of those plans substitute some benefits for those in separate EHB categories. However, we anticipate that this additional time and effort will be limited because issuers must meet the requirement at § 156.115(b)(3)(i) to provide benefits that are substantially equal to their State's EHB-benchmark plan. The impact on consumers of the substituted benefits themselves will be mixed—some consumers stand to benefit by gaining access to benefits they desire that would not have been provided without this policy, while other consumers may find that a particular issuer no longer offers benefits they desire. Benefits no longer offered by one issuer, however, may be offered by another issuer. The net effect is uncertain.

15. Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

We are removing AV level of coverage requirements for SADP issuers for coverage of pediatric dental EHB, however we are maintaining the AV certification requirement at revised § 156.150(b)(2) and codifying an operational requirement that such certification be reported to the Exchange, which issuers of SADPs have already been fulfilling, as part of the QHP certification process. We estimate that the change in AV could lead to a reduction in premiums for certain SADPs. Issuers may choose to offer more SADPs at varying premiums and levels of coverage. The offering of more SADPs and SADPs with lower premiums may lead to increased enrollment in SADPs. Because certain eligible taxpayers can use PTC to pay for the portion of SADP premiums attributable to EHB, a reduction in premiums will likely reduce the premium for purposes of the PTC, leading to a small transfer from credit recipients to the government. If enrollment increases due to potentially lower premiums there may be an overall increase in the total PTC payments by the government. The net effect is uncertain. While the requirement to report a SADP's AV is newly codified in regulation, issuers of SADPs previously reported level of coverage as part of the QHP certification process, so this change is not expected to have an impact on issuers' reporting burden.

16. Qualified Health Plan Certification

For plan years 2019 and later, we proposed to further expand the role of States in the QHP certification process for FFEs, including FFEs where the State performs plan management functions. Specifically, we proposed to defer to States for additional review areas, including accreditation requirements at § 156.275, compliance reviews at § 156.715, minimum geographic area of the plan's service area at § 155.1055, and quality improvement strategy reporting at § 156.1130, if feasible and appropriate. We received comments that this policy would impose burdens on States, particularly those States that are not performing these reviews, and we are not finalizing this proposal for these four review areas. Some States commented that they presently lack resources, including staffing resources, to conduct these reviews. We are finalizing a policy to extend for the 2019 benefit year and beyond the QHP certification review standards related to network adequacy and ECPs that we finalized in the Market Stabilization rule. We do not anticipate this policy will increase burden on States because we believe these reviews are already being performed by States. We anticipated slight reduction in burden for issuers due to not needing to undergo duplicative reviews and a reduction in costs to the Federal government. We sought comment on whether there are burdens we are not considering. While commenters expressed concern that these policies could increase burden for consumers to obtain care from needed providers, we believe that State reviews related to network adequacy are capable of adequately preserving consumer access to care from such providers.

We are removing the meaningful difference standard at § 156.298. Issuers will have a potential reduction in administrative costs since they will no longer have to implement their internal assessments as to whether their plan offerings meet this standard. We acknowledged and commenters noted that consumers may have more QHPs to select from which may increase the burden in selecting a QHP. However, we do not have evidence from any Exchange that removing the meaningful difference standard creates any new burden on consumers.

We also anticipate that the removal of the meaningful difference standard will reduce the regulatory burden on SBE–FPs. Under § 155.200(f)(2)(iv), SBE–FPs are required to establish and oversee requirements for their issuers that are no less stringent than the meaningful difference standard as it applies to issuers participating in the FFEs. SBE–FPs will no longer need to establish such a standard or oversee it.

We are removing the requirements for SBE–FPs to enforce FFE standards for network adequacy at § 155.200(f)(2)(ii) and essential community providers at § 155.200(f)(2)(iii). We anticipate that SBE–FPs will have a potential reduction in administrative costs since they will have the flexibility to determine how to implement the network adequacy and essential community provider standards with which issuers offering QHPs through the SBE–FP must comply. We believe SBE–FPs are best positioned to determine these standards for the QHP certification process in their States, and that the removal of the requirement that SBE–FPs establish and oversee requirements for their issuers that are no less strict that the manner in which these regulatory requirements are applied to FFE issuers will streamline certain aspects of the QHP certification process, reduce issuer burden, and return traditional insurance market regulatory authority to the States.

17. Provisions Related to Cost Sharing (§ 156.130)

The PPACA provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance helps many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.[105]

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 on their AVs of the reductions described in the PPACA to the estimated 2019 maximum annual limitation on cost sharing for self-only coverage. We do not believe these changes will result in a significant economic impact. Therefore, we do not believe the provisions related to cost-sharing reductions in this final rule will have an impact on the program established by and described in past Payment Notices.

We also finalized the premium adjustment percentage for the 2019 benefit year. Under § 156.130(e), and 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 the percentage (if any) by which the average per enrollee premium for employer-sponsored health insurance coverage for the preceding calendar year exceeds such average per enrollee premium for employer-sponsored health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the PPACA: 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 sections 4980H(a) and 4980H(b) of the Code. We believe that the 2019 premium adjustment percentage is well within the parameters used in the modeling of the PPACA, and we do not expect that these provisions will alter CBO's March 2016 baseline estimates of the budget impact.

18. Minimum Essential Coverage (§ 156.602, § 156.604)

We proposed to designate CHIP buy-in programs that provide identical coverage to the CHIP program under title XXI of the Act in the applicable State as minimum essential coverage. This final rule does not provide categorical designation of CHIP buy-in programs as minimum essential coverage. States will have the option of electronically submitting to HHS information regarding their plans and, after review and comparison of the coverage, HHS will verify whether or not the CHIP buy-in programs provide at least the same coverage as the title XXI CHIP programs, such that they statutorily qualify as minimum essential coverage. Currently, very few States offer CHIP buy-in programs, and such plans in two States have applied for and been recognized as minimum essential coverage. Of the States that opt into the verification process, there will be a reduction in burden related to making changes to their plans to provide at least the same coverage as the title XXI CHIP program.

19. Medical Loss Ratio (Part 158)

We are amending § 158.221(b) to allow issuers the option to report a single quality improvement activity expense amount equal to 0.8 percent of earned premium, in lieu of reporting the actual QIA amounts in five separate categories described in § 158.150(b)(2)(i)–(v). Based on MLR data for the 2015 MLR reporting year, HHS estimates that the amendment will decrease rebate payments from issuers to consumers by approximately $23 million.

We are also amending several sections of 45 CFR part 158, subpart C (§§ 158.301, 158.321–158.322, 158.330, 158.341, 158.350) to modify the process and criteria for the Secretary to determine whether to adjust the 80 percent MLR standard in the individual market in a State. While it is uncertain what specific adjustments States may request, most adjustments previously granted by the Secretary have ranged from 70 to 75 percent. Based on MLR data for the 2015 MLR reporting year, and assuming that 22 States will request an adjustment (including 17 States that previously requested adjustments prior to 2014), HHS estimates that the amendments will decrease rebate payments from issuers to consumers or increase premiums paid by consumers to issuers by approximately $52 million (assuming a reduction of the 80 percent MLR standard to 75 percent for all 22 States) to $64 million (assuming a reduction of the MLR standard to 70 percent for all 22 States) annually, for up to 3 years at a time. This represents an estimated 74 percent to 91 percent reduction, respectively, in rebates payable in those 22 States, which together accounted for $70 million out of the nationwide total $107 million in rebates that issuers owed to individual market consumers for 2015. The actual reduction in rebates may be lower or higher depending on which States apply for an adjustment, and whether and how much the Secretary may adjust the individual market MLR standard in each State.

20. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the proposed rule will be the number of reviewers of this final rule. We acknowledge that this

[105] 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*.

assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule.

We are required to promulgate a substantial portion of this rule each year under our regulations and we estimate that approximately half of the remaining provisions will cause additional regulatory review burden that stakeholders do not already anticipate. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that we are required to promulgate each year.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits.[106] Assuming an average reading speed, we estimate that it will take approximately 1 hour for the staff to review the relevant portions of this proposed rule that causes unanticipated burden. We received 416 comments, including 99 comments that were substantially similar to one of four different letters, resulting in 322 unique comments on the proposed rule. We assume that for form letters, only the staff at the organization that arranged for those letters will review the final rule. For each entity that reviews the rule, the estimated cost is $105.16. Therefore, we estimate that the total cost of reviewing this regulation is approximately $33,862 ($105.16 × 322 reviewers). This may underestimate the review costs, since not all reviewers may have submitted comments. In addition, stakeholders that will need to do a detailed analysis in order to implement the unanticipated provisions of this rule will need additional time and personnel, which will vary depending on the extent to which they are affected. To estimate an upper bound, we assumed that on average 530 issuers and 50 States will spend 10 hours each, 100 other organizations will spend 5 hours each and 100 individuals will spend 1 hour each to review the rule. Under these assumptions, total time spent reviewing the rule would be 6,400 hours with an estimated cost of approximately $673,024.

D. Regulatory Alternatives Considered

In developing the policies contained in the final rule, we considered numerous alternatives to the policies being finalized. Below, we discuss the key regulatory alternatives that we considered.

For the 2019 benefit year, we considered using only the 2016 benefit year enrollee-level EDGE data to recalibrate the risk adjustment model coefficients. However, this could lead to uncertainty in issuers' expectation of risk adjustment transfers due to the sole use of a new dataset for recalibrating the model coefficients. We believe that blending multiple years of data will promote stability for the risk adjustment coefficients year-to-year, particularly for rare conditions with small sample sizes. Therefore, we proposed to blend coefficients calculated from the 2016 benefit year enrollee-level EDGE data with 2014 and 2015 MarketScan® data. Additionally, given the timing of the proposed rule, we were unable to analyze the 2016 enrollee-level EDGE data in time to publish the coefficients calibrated using the EDGE data in the proposed rule. Similar to the 2018 benefit year final risk adjustment coefficients, we considered publishing the 2019 benefit year final risk adjustment coefficients in guidance after the publication of the final rule with more recent MarketScan® data that will become available at the end of this year. However, the 2016 benefit year enrollee-level risk adjustment data was available in time to complete our analysis and publish the final coefficients in this rule. Additionally, we considered but did not propose to use the 2016 MarketScan® data that will become available at the end of this year for the 2019 benefit year risk adjustment model recalibration. We also considered assigning higher weights to the coefficients solved from more recent data, however, to allow stability in the market have equally blended the 3 years of data. We are finalizing the 2019 benefit year model coefficients blended with 2016 EDGE data, and 2014 and 2015 MarketScan® data published in this rule.

For the State flexibility to request reductions of other applicable risk adjustment transfers, we considered alternate requirements for States requesting a reduction. We considered requiring actuarially certified standards, State's attestation noting consensus from all issuers of risk adjustment covered plans in the State's market, or simulation studies demonstrating the effect of the reduction on State's market risk pool. We determined that to ensure issuers are adequately compensated for the actuarial risk of their enrollees and do not have incentives to avoid higher risk enrollees, the State regulators need to submit evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State's market. States must also justify the percentage reduction by providing evidence and analysis demonstrating the State-specific factors and the percentage by which those factors warrant an adjustment to more precisely account for the differences in actuarial risk in the State's market as compared to the national norm, or demonstrating the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a *de minimis* effect on the necessary premium increase to cover the affected issuer's or issuers' reduced payments. We also considered only making the flexibility available to States in the small group market, but determined that just as with the States' small group markets, it is possible that the national methodology may not precisely account for unique State market dynamics in the individual or merged markets.

For the risk adjustment data validation program, HHS considered alternate approaches for evaluating error rates and adjusting risk scores when an error rate deviates from a statistically significant value. We considered calculating a national central tendency of errors and then adjusting risk scores only when an error rate that falls outside of the confidence interval around the national central tendency; however, we determined that the evaluation of error rates relative to a national average would likely result in significantly less accurate risk score adjustments, primarily because it would not account for differences in error rates due to issuer size or the distribution of HCCs in the enrollee population.

We considered maintaining the current applicability of the Federal rate review requirements, and continuing to review the reasonableness of student health insurance coverage rate increases subject to review. However, this rule will provide States with greater flexibility to meet the needs of their markets and reduce the burden associated with review of plans that are not part of the single risk pool. As a practical matter, student health insurance coverage has generally been given the same plan design flexibility as

[106] *https://www.bls.gov/oes/current/oes_nat.htm.*

plans in the large group market. Just like purchasers of large group plans, purchasers in the student market are viewed as more sophisticated, with greater leverage and ability to avoid the imposition of unreasonable rate increases. Single risk pool pricing, the primary focus of the rate review program, does not apply to student health insurance coverage.

We considered maintaining the current 30-day notice requirement for States to notify HHS prior to posting the required information on proposed and final rate increases. However, such advanced notice may be impractical in some States so we have decreased the notice requirement to 5 business days. We considered permitting States to post the required information on rate increases on a rolling basis. However, we agree with the concerns shared by the majority of public comments opposing that proposal, so we are maintaining the uniform posting requirement.

In adding standards for § 155.221, HHS considered making no changes to the existing rule and retaining the existing standard for agents and brokers to contract with a third-party entity approved by HHS for conducting audits under the section. In finalizing the proposal, we continue to believe that it is necessary to include issuers and to provide the necessary flexibility in oversight that both protects consumers and encourages enrollment pathway innovation for agents, brokers, and issuers using direct enrollment.

For the amendments to § 155.320, we considered developing a comprehensive database using information from employers on the plans they offer to their employees and their family members that could satisfy verification requirements under paragraph (d)(2) for all Exchanges. This approach would be resource-intensive for Exchanges, and would produce a database with limited utility due to data limitations. Developing a database; recruiting and educating employers to participate in voluntarily submitting the data; and providing technical assistance to employers for the first year of implementation on how to input the data is estimated to cost at least $38 million. Building such a database would also rely on the voluntary participation of substantially all employers. This participation would be onerous for employers. Employers would need to provide individual employee level data regarding plans the employer will offer, information that may not be available in time to populate a comprehensive database prior to the Exchange's plan year. In addition, since the PPACA does not require employers to provide to the Exchange the relevant information on what coverage they offer, Exchanges and HHS would not receive data from all employers. After weighing our options, we decided that this approach would be overly costly and burdensome, and of limited value due to gaps in the data Exchanges and HHS would be able to collect. We also considered removing the requirement to connect to an HHS-approved data source, and the requirement to use an alternative method if the Exchange does not connect to the required data sources, but were concerned about the potential impact on program integrity.

In finalizing the policy related to the SHOP enrollment process, we considered maintaining the status quo, but believe that the increase in flexibility, cost savings and reduction in burden resulting from the new enrollment approach, will have a positive impact on small businesses across the country and provide States with needed flexibility.

In finalizing the policy for the new EHB-benchmark plan selection options described at § 156.111, we considered a variety of alternatives, including maintaining the current EHB-benchmark policy without modification. Although maintaining the current policy would have promoted stability by preserving the current EHB-benchmarks across all States, we do not believe it would have offered the additional flexibility that States have requested in selecting an EHB-benchmark plan to best meet the needs of their consumer population. We also considered whether it was feasible to offer States increased flexibility by allowing them to set a range of acceptable EHB within their State, such that issuers could offer plans within that range with more limited EHB coverage or more robust EHB coverage. However, we determined that this option did not meet statutory requirements. To balance stability, flexibility, and statutory requirements, we instead finalized the proposal to offer States the expanded EHB-benchmark plan selection options at § 156.111, as well as the option to default to the State's current EHB-benchmark plan. We believe this approach will provide States with the opportunity to take advantage of greater flexibility in selecting an EHB-benchmark plan while also providing those States that value stability with the option to retain their current benchmark plan.

With respect to the provision regarding removing the AV requirement for SADPs, we considered making no change or proposing an expansion to the de minimis range to mirror the expanded de minimis range for QHPs (−4/+2 percentage points) or of +/−3 percentage points. We determined that these alternatives were less desirable because they do not provide issuers with as much flexibility to offer a range of SADPs as the proposed removal of the AV standards for SADPs. We finalized the policy to remove the level of coverage AV requirement for SADPs as proposed, but retained a requirement to certify AV and codified an operational requirement that such certification be reported to the Exchange, which SADP issuers already have been doing, as part of the QHP certification process. For the QHP certification standard regarding meaningful difference, we considered maintaining the requirement on issuers, but we believe that removing this provision will promote the offering of a variety of affordable QHPs that will meet consumers' needs, will provide issuers with more flexibility, and will remove an unnecessary regulatory requirement.

For the amendments to § 158.221(b), we considered retaining the current quality improvement activity reporting requirements, since giving issuers the option to report a standardized rate for QIA expenditures may inhibit HHS from being able to analyze trends in issuers' investment in improving the quality of health care in the future, and may also reduce rebates to consumers by allowing issuers to effectively increase their MLRs by 0.8 percent even if those issuers engaged in and spent only trivial amounts on QIA. However, this change will also potentially level the playing field among issuers to a certain extent and lead to more accurate rebate payments, since many issuers likely do engage in QIA but forego reporting that spending because the burden of analyzing, documenting, tracking, allocating, and reporting QIA expenses exceeds the benefits for MLR purposes. Because the finalized approach of giving issuers the option to report a minimal, standardized rate will reduce unwarranted regulatory and economic burdens for issuers that do not want to track and report the exact QIA amounts for their MLR calculation, we believe that the finalized approach will be more effective and represents a better balance than the current requirements.

For the amendments to part 158, subpart C, we considered retaining the current requirements for States to request an adjustment to the 80 percent MLR standard in the individual market in a State. However, HHS recognizes that many of the current State application requirements are burdensome and less relevant in the

post-2014 reformed environment, and may preclude or discourage States from proposing innovative solutions to help stabilize their individual markets. Therefore, we believe the finalized amendments will reduce regulatory burdens on States, and provide States with an additional tool to promote stability in their individual markets.

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. 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.

This final rule includes standards for the risk adjustment and risk adjustment data validation programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this final rule:

- Health insurance issuers.
- Group health plans.

We believe that health insurance issuers and group health plans will 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 may 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.[107] We believe that few, if any, insurance companies selling comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds.

This final rule will allow enrollment in a SHOP QHP through a SHOP-registered agent or broker, or through a participating QHP issuer. The SHOPs are generally limited by statute to employers with at least one but not more than 50 employees, unless a State opts to provide that employers with from 1 to 100 employees are ''small employers.'' For this reason, we expect that many employers who will be affected by the finalized policies will meet the SBA standard for small entities. We do not believe that the finalized policies impose requirements on employers offering health insurance through a SHOP that are more restrictive than the current requirements on small businesses offering employer sponsored insurance. We believe the processes that we have established constitute the minimum amount of requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives can be developed to further lessen the compliance burden.

Based on data from MLR annual report submissions for the 2015 MLR reporting year, approximately 92 out of over 530 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 50 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. We estimate that 57 of these 92 potentially small entities may experience a decrease in the rebate amount owed to consumers under the amendments to the quality improvement activity reporting provisions in part 158, and 27 of these 57 entities are part of larger holding groups. In addition, we estimate that no small entities will be impacted by the amendments to 45 CFR part 158, subpart C. Therefore, we believe that the provisions of this final rule regarding MLR will not affect a substantial number of small entities, and further, the impact of the proposed QIA provisions on small entities will be positive.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $148 million. Although we have not been able to quantify all costs, we expect the combined impact on State, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

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 rule, HHS attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For States that elected previously to operate an Exchange, or risk adjustment program, much of the initial cost of creating these programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the

[107] ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes'', effective February 26, 2016, U.S. Small Business Administration, available at *https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/table-smallbusiness-size-standards.*

State. Current State Exchanges charge user fees to issuers.

In HHS's view, while this final rule will not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, we are finalizing proposals to provide States with substantially more flexibility in selecting an EHB-benchmark plan, to explore ways to make it easier for States to establish and maintain a State Exchange, to provide States with substantially more flexibility in how they operate a SHOP, to provide States with the option to request a reduction to risk adjustment transfers in their small group market; and to make it easier for States to apply for and be granted an adjustment to the MLR standard in their State. We are also returning flexibility to States in their review of rate increases. We are also finalizing the proposal to give States the choice to review rate increases for student health insurance coverage. We are also reducing the advanced notification that States must give HHS about the posting of rate increases from 30 days to 5 business days. Finally, States will no longer be required to seek approval if the State-specific threshold for reasonableness review is lower than the Federal default rate review threshold.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller for review.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This final rule is an E.O. 13771 deregulatory action.[108]

List of Subjects

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, 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 interests, Consumer protection, Grants 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, Advisory committees, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, 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 amends 45 CFR parts 147, 153, 154, 155, 156, 157 and 158 as set forth below.

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

■ 1. 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.

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

§ 147.102 Fair health insurance premiums.

* * * * *

(c) * * *

(3) * * *

(iii) * * *

(D) To the extent permitted by applicable State law and, in the case of coverage offered through a SHOP, as permitted by the SHOP, apply this paragraph (c)(3)(iii) uniformly among group health plans enrolling in that product, giving those group health plans the option to pay premiums based on average enrollee premium amounts.

* * * * *

■ 3. Section 147.104 is amended by—

■ a. Revising paragraphs (b)(1)(i)(B), (b)(1)(i)(C) and (b)(1)(ii);

■ b. Removing paragraph (b)(1)(iii); and

■ c. Revising paragraphs (b)(2)(i) introductory text and (ii).

The revisions read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(1) * * *

(i) * * *

[108] We estimate cost savings of approximately $52.74 million in 2018, $58.12 million in 2019, and annual cost savings of $4.12 million thereafter. Thus the annualized value of cost savings, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, is $9.26 million.

(B) In the case of a group health plan in the small group market that cannot comply with employer contribution or group participation rules for the offering of health insurance coverage, as allowed under applicable State law, and in the case of a QHP offered in the SHOP, as permitted by § 156.285(e) or § 156.286(e) of this subchapter, a health insurance issuer may restrict the availability of coverage to an annual enrollment period that begins November 15 and extends through December 15 of each calendar year.

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a SHOP in a State, for a group enrollment received on the first through the fifteenth day of any month, the coverage effective date must be no later than the first day of the following month. For a group enrollment received on the 16th through last day of any month, the coverage effective date must be no later than the first day of the second following month. In either such case, a small employer may instead opt for a later effective date within a quarter for which small group market rates are available.

(ii) *Individual market.* A health insurance issuer in the individual market must allow an individual to purchase health insurance coverage during the initial and annual open enrollment periods described in § 155.410(b) and (e) of this subchapter. Coverage must become effective consistent with the dates described in § 155.410(c) and (f) of this subchapter.

(2) * * *

(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, with respect to coverage offered outside of an Exchange, the following:

* * * * *

(ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in § 155.420(a)(5)) 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.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 4. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

■ 5. Section 153.320 is amended by adding paragraph (d) to read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(d) *State flexibility to request reductions to transfers.* Beginning with the 2020 benefit year, States can request to reduce risk adjustment transfers in the State's individual, small group or merged markets by up to 50 percent in States where HHS operates the risk adjustment program.

(1) *State requests.* State requests for a reduction to transfers must include:

(i) Supporting evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State market;

(ii) The adjustment percentage of up to 50 percent requested for the State individual, small group or merged market; and

(iii) A justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual, small group or merged market, or demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(2) *Timeframe to Submit Reduction Requests.* States must submit requests for a reduction to transfer in the individual, small group or merged market by August 1 of the year, 2 calendar years prior to the applicable benefit year in the form and manner specified by HHS.

(3) *Publication of Reduction Requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters proposed rule and make the supporting evidence available to the public for comment. HHS will publish any approved State reduction requests or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule.

(4) *HHS approval.* (i) Subject to paragraph (d)(4)(ii) of this section, HHS will approve State requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market, and relevant public comments:

(A) That State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State individual, small group or merged market and support the percentage reduction to risk adjustment transfers requested; or

(B) That State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual, small group or merged market and the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(ii) HHS may approve a reduction amount that is lower than the amount requested by the State if the supporting evidence and analysis do not fully support the requested reduction amount. HHS will assess other relevant factors, including the premium impact of the transfer reduction for the State market.

■ 6. Section 153.630 is amended by revising paragraphs (b)(6), (8), and (9) to read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(6) An issuer must provide the initial validation auditor and the second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission. Notwithstanding any other provision of this section, a qualified provider that is licensed to diagnose mental illness by the State and that is prohibited from furnishing a complete medical record by applicable State privacy laws concerning any enrollee's treatment for one or more mental or behavioral health conditions may furnish a signed mental or behavioral health assessment that, to the extent permissible under applicable Federal and State privacy laws, should contain: The enrollee's name; sex; date of birth; current status of all mental or behavioral health diagnoses; and dates of service. The mental or behavioral health assessment should be signed by the provider and submitted with an attestation that the provider is prohibited from furnishing a complete medical record by applicable State privacy laws.

* * * * *

(8) The initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. The initial validation auditor must achieve a consistency measure of at least 95 percent for his or her review outcomes, except that for validation of risk adjustment data for the 2015 and 2016 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805(b) through (e) of this subchapter if an issuer of a risk adjustment covered plan—

(i) Fails to engage an initial validation auditor;

(ii) Fails to submit the results of an initial validation audit to HHS;

(iii) Engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or

(iv) Intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS.

* * * * *

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 7. 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).

■ 8. Section 154.103 is amended by revising paragraph (b) to read as follows:

§ 154.103 Applicability.

* * * * *

(b) *Exceptions.* The requirements of this part do not apply to—

(1) Grandfathered health plan coverage as defined in § 147.140 of this subchapter;

(2) Excepted benefits as described in section 2791(c) of the PHS Act; and

(3) For coverage effective on or after July 1, 2018, student health insurance coverage as defined in § 147.145 of this subchapter.

■ 9. Section 154.200 is revised to read as follows:

§ 154.200 Rate increases subject to review.

(a) A rate increase filed in a State, or effective in a State that does not require a rate increase to be filed, is subject to review if:

(1) The rate increase is 15 percent or more applicable to a 12-month period that begins on January 1, as calculated under paragraph (b) of this section; or

(2) The rate increase meets or exceeds a State-specific threshold applicable to a 12-month period that begins on January 1, as calculated under paragraph (b) of this section, determined by the Secretary. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that the data relating to such State-specific factors are available by August 1 of the preceding year. States interested in proposing a State-specific threshold greater than the Federal default stated in paragraph (a)(1) of this section are required to submit a proposal for approval of such threshold to the Secretary by August 1 of the preceding year, in the form and manner specified by the Secretary.

(b) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if the average increase, including premium rating factors described in § 147.102 of this subchapter, for all enrollees weighted by premium volume for any plan within the product meets or exceeds the applicable threshold.

(c) If a rate increase that does not otherwise meet or exceed the threshold under paragraph (b) of this section meets or exceeds the threshold when combined with a previous increase or increases during the 12-month period preceding the date on which the rate increase would become effective, then the rate increase must be considered to meet or exceed the threshold and is subject to review under § 154.210, and such review shall include a review of the aggregate rate increases during the applicable 12-month period.

■ 10. Section 154.215 is amended by revising paragraph (h)(2) to read as follows:

§ 154.215 Submission of rate filing justification.

* * * * *

(h) * * *

(2) CMS will make available to the public on its website the information contained in Parts I and III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information as defined in HHS's Freedom of Information Act regulations, 45 CFR 5.31(d).

* * * * *

■ 11. Section 154.301 is amended by revising paragraph (b)(2) to read as follows:

§ 154.301 CMS's determinations of Effective Rate Review Programs.

* * * * *

(b) * * *

(2) If a State intends to make the information in paragraph (b)(1)(i) of this section available to the public prior to the date specified by the Secretary, or if it intends to make the information in paragraph (b)(1)(ii) of this section available to the public prior to the first day of the annual open enrollment period in the individual market for the applicable calendar year, the State must notify CMS in writing, no later than five (5) business days prior to the date it intends to make the information public, of its intent to do so and the date it intends to make the information public.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 12. 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).

■ 13. Section 155.106 is amended by revising paragraph (c) introductory text to read as follows:

§ 155.106 Election to operate an Exchange after 2014.

* * * * *

(c) *Process for State Exchanges that seek to utilize the Federal platform for select functions.* States may seek approval to operate a State Exchange utilizing the Federal platform for only the individual market. A State seeking approval to operate a State Exchange utilizing the Federal platform for the individual market to support select functions through a Federal platform agreement under § 155.200(f) must:

* * * * *

■ 14. Section 155.200 is amended by removing and reserving paragraphs (f)(2)(ii) through (iv); and revising paragraph (f)(4) introductory text to read as follows;

§ 155.200 Functions of an Exchange.

* * * * *

(f) * * *

(2) * * *

(ii) [Reserved]

(iii) [Reserved]

(iv) [Reserved]

* * * * *

(4) A State Exchange on the Federal platform that utilizes the Federal

platform for SHOP functions, for plan years beginning on or after January 1, 2018, must require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a Federally-facilitated SHOP under § 155.706(b)(6)(i)(A). A State Exchange on the Federal platform that utilizes the Federal platform for SHOP functions, as set forth in paragraphs (f)(4)(i) through (vii) of this section, for plan years beginning prior to January 1, 2018, must—

* * * * *

■ 15. Section 155.210 is amended by revising paragraphs (c)(2) introductory text and (e)(7) to read as follows:

§ 155.210 Navigator program standards.

* * * * *

(c) * * *

(2) The Exchange must include an entity from at least one of the following categories for receipt of a Navigator grant:

* * * * *

(e) * * *

(7) In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a Navigator solely because its principal place of business is outside of the Exchange service area;

* * * * *

■ 16. Section 155.215 is amended by revising paragraph (h) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(h) *Physical presence.* In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a non-Navigator entity or as non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area.

* * * * *

■ 17. Section 155.221 is revised to read as follows:

§ 155.221 Standards for third-parties to perform audits of agents, brokers, and issuers participating in direct enrollment.

(a) An agent, broker, or issuer participating in direct enrollment must engage a third-party entity to conduct an annual review to demonstrate operational readiness in accordance with § 155.220(c)(3)(i)(K) and with § 156.1230(b)(2) of this subchapter. The third-party entity will be a downstream or delegated entity of the agent, broker or issuer that participates or wishes to participate in direct enrollment.

(b) An agent, broker, or issuer participating in direct enrollment must satisfy the requirement to demonstrate operational readiness under paragraph (a) of this section by engaging a third-party entity that meets each of the following standards:

(1) Has experience conducting audits or similar services, including experience with relevant privacy and security standards;

(2) Adheres to HHS specifications for content, format, privacy, and security in the conduct of an operational readiness review, which includes ensuring that agents, brokers, and issuers are in compliance with the applicable privacy and security standards and other applicable requirements;

(3) Collects, stores, and shares with HHS all data related to the third-party entity's audit of agents, brokers, and issuers in a manner, format, and frequency specified by HHS until 10 years from the date of creation, and complies with the privacy and security standards HHS adopts for agents, brokers, and issuers as required in accordance with § 155.260;

(4) Discloses to HHS any financial relationships between the entity and individuals who own or are employed by an agent, broker, or issuer for which it is conducting an operational readiness review.

(5) Complies with all applicable Federal and State requirements;

(6) Ensures, on an annual basis, that appropriate staff successfully complete operational readiness review training as established by HHS prior to conducting audits under paragraph (a) of this section;

(7) Permits access by the Secretary and the Office of the Inspector General or their designees in connection with their right to evaluate through audit, inspection, or other means, to the third-party entity's books, contracts, computers, or other electronic systems, relating to the third-party entity's audits of agent's, broker's, or issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the date of creation; and

(8) Complies with other minimum business criteria as specified in guidance by HHS.

(c) An agent, broker or issuer may engage multiple third-party entities to conduct the audit under paragraph (a) of this section and each third-party entity must satisfy the standards outlined under paragraph (b) of this section.

■ 18. Section 155.305 is amended by revising paragraph (f)(4) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(4) *Compliance with filing requirement.* The Exchange may not determine a tax filer eligible for APTC if HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that APTC 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.

* * * * *

■ 19. Section 155.320 is amended by—

■ a. Revising paragraphs (c)(3)(iii) introductory text, and paragraph (c)(3)(iii)(A);

■ b. Adding paragraphs (c)(3)(iii)(D) through (F);

■ c. Revising paragraph (c)(3)(vi)(C), (D), (F) and (G); and

■ d. Revising paragraph (d)(4) introductory text.

The revisions and additions read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(3) * * *

(iii) *Verification process for changes in household income.* (A) Except as specified in paragraph (c)(3)(iii)(B), (C), and (D) of this section, if an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(ii)(A) of this section for the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation regarding a tax filer's annual household income without further verification.

* * * * *

(D) If an applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested and is more than a reasonable threshold above the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, the data described in paragraph (c)(3)(ii)(A) of this section indicates that projected annual household income is under 100 percent FPL, and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must proceed in accordance with § 155.315(f)(1) through (4). However, this paragraph (c)(3)(iii)(D) does not apply if the applicant is a non-citizen who is lawfully present and ineligible for Medicaid by reason of immigration status. For the purposes of this paragraph, a reasonable threshold is established by the Exchange in guidance and approved by HHS, but must not be less than 10 percent, and can also include a threshold dollar amount.

(E) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), and implement such determination in accordance with the effective dates specified in § 155.330(f).

(F) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in § 155.330(f).

* * * * *

(vi) * * *

(C) *Increases in annual household income.* If an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(vi)(A) of this section to the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation for the tax filer's family without further verification, unless:

(*1*) The Exchange finds that an applicant's attestation of a tax filer's annual household income is not reasonably compatible with other information provided by the application filer, or

(*2*) The data described in paragraph (c)(3)(vi)(A) of this section indicates that projected annual household income is under 100 percent FPL and the applicant's attestation to projected household income, as described in paragraph (c)(3)(ii)(B) of this section, is greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested and is more than a reasonable threshold above the annual household income as computed using data sources described in paragraph (c)(3)(vi)(A) of this section, in which case the Exchange must follow the procedures specified in § 155.315(f)(1) through (4). The reasonable threshold used under this paragraph must be equal to the reasonable threshold established in accordance with paragraph (c)(3)(iii)(D) of this section.

(D) *Decreases in annual household income and situations in which electronic data is unavailable.* If electronic data are unavailable or an applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is more than a reasonable threshold below the annual household income as computed using data sources described in paragraphs (c)(3)(vi)(A) of this section, the Exchange must follow the procedures specified in § 155.315(f)(1) through (4). The reasonable threshold used under this paragraph must be equal to the reasonable threshold established in accordance with paragraph (c)(3)(vi) of this section.

* * * * *

(F) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), and implement such determination in accordance with the effective dates specified in § 155.330(f).

(G) If, at the conclusion of the period specified in § 155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation for the tax filer and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirement specified in § 155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in § 155.330(f).

* * * * *

(d) * * *

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange must follow the procedures specified in paragraph (d)(4)(i) of this section or, for benefit years 2016 through 2019, the Exchange may follow the procedures specified in paragraph (d)(4)(ii) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraph (d)(2)(i) of this section.

* * * * *

■ 20. Section 155.420 is amended by:
■ a. Revising paragraphs (a)(4)(iii), (a)(5) and (b)(2)(i);
■ b. Removing paragraph (b)(2)(v);
■ c. Redesignating paragraph (b)(2)(vi) as paragraph (b)(2)(v);
■ d. Revising paragraph (d)(1)(iii); and
■ e. Revising paragraph (d)(10)(i).

The revisions read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), (d)(6)(i) and (ii) of this section for becoming newly eligible for CSRs, (d)(8), (9), (10) and (12) of this section:

(A) If an enrollee qualifies for a special enrollment period, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter; or

(B) If a dependent qualifies for a special enrollment period, and an enrollee is adding the dependent to his or her QHP, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter, or enroll the new qualified individual in a separate QHP.

(5) *Prior coverage requirement.* Qualified individuals who are required to demonstrate coverage in the 60 days prior to a qualifying event can either demonstrate that they had minimum essential coverage as described in 26 CFR 1.5000A–1(b) for 1 or more days during the 60 days preceding the date of the qualifying event; lived in a foreign country or in a United States territory for 1 or more days during the 60 days preceding the date of the qualifying event; are an Indian as defined by section 4 of the Indian Health Care Improvement Act; or lived for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420, in a service area where no qualified health plan was available through the Exchange.

(b) * * *

(2) * * *

(i) In the case of birth, adoption, placement for adoption, placement in foster care, or child support or other court order as described in paragraph (d)(2)(i) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, placement in foster care, or effective date of court order; or it may permit the qualified individual or enrollee to elect a coverage effective date of the first of the month following plan selection; or in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date of either the first of the month following the date of plan selection or in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly selected by the qualified individual or enrollee.

* * * * *

(d) * * *

(1) * * *

(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)) or loses access to health care services through coverage provided to a pregnant woman's unborn child, based on the definition of a child in 42 CFR 457.10. The date of the loss of coverage is the last day the qualified individual would have pregnancy-related coverage or access to health care services through the unborn child coverage; or

* * * * *

(10) * * *

(i) Is a victim of domestic abuse or spousal abandonment as defined by 26 CFR 1.36B–2 or a dependent or unmarried victim within a household, is enrolled in minimum essential coverage, and sought to enroll in coverage separate from the perpetrator of the abuse or abandonment; or

* * * * *

■ 21. Section 155.430 is amended by:

■ a. Revising paragraph (d)(2)(ii);

■ b. Redesignating paragraphs (d)(2)(iii), (d)(2)(iv) and (d)(2)(v) as paragraphs (d)(2)(iv), (d)(2)(v), and (d)(2)(vi), respectively;

■ c. Adding new paragraph (d)(2)(iii); and

■ d. Revising newly redesignated paragraphs (d)(2)(iv), and (v).

The revisions and additions read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(d) * * *

(2) * * *

(ii) If the enrollee does not provide reasonable notice, fourteen days after the termination is requested by the enrollee; or

(iii) At the option of the Exchange, on the date on which the termination is requested by the enrollee, or on another prospective date selected by the enrollee; or

(iv) If an Exchange does not require an earlier termination date in accordance with paragraph (d)(2)(iii) of this section, at the option of the QHP issuer, on a date on or after the termination is requested by the enrollee that is less than 14 days after the termination is requested by the enrollee, if the enrollee requests an earlier termination date; or

(v) At the option of the Exchange, for an individual who is newly determined eligible for Medicaid, CHIP, or the Basic Health Program, if a Basic Health Program is operating in the service area of the Exchange, the day before the enrollee's date of eligibility for Medicaid, CHIP, or the Basic Health Program.

* * * * *

■ 22. Section 155.500 is amended by revising the definitions of ''Appeal request'' and ''Appeals entity'' to read as follows:

§ 155.500 Definitions.

* * * * *

Appeal request means a clear expression, either orally or in writing, by an applicant, enrollee, employer, or small business employer or employee to have any eligibility determination or redetermination contained in a notice issued in accordance with § 155.310(g), § 155.330(e)(1)(ii), § 155.335(h)(1)(ii), § 155.610(i), § 155.715(e) or (f), or § 155.716(e) reviewed by an appeals entity.

Appeals entity means a body designated to hear appeals of eligibility determinations or redeterminations contained in notices issued in accordance with § 155.310(g), § 155.330(e)(1)(ii), § 155.335(h)(1)(ii), § 155.610(i), § 155.715(e) and (f), or § 155.716(e).

* * * * *

■ 23. Section 155.605 is amended by revising paragraph (d)(2)(iv) to read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(d) * * *

(2) * * *

(iv) For an individual who is ineligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage in accordance with section 5000A(e)(1)(B)(ii) of the Code, inclusive of all members of the family, as defined in 26 CFR 1.36B–1(d), who have not otherwise been granted an exemption through the Exchange and who are not treated as eligible to purchase coverage under an eligible employer-sponsored plan, in accordance with paragraph (d)(4)(ii) of this section. If there is not a bronze level plan offered through the Exchange in the

individual's county, the Exchange must use the annual premium for the lowest cost Exchange metal level plan, excluding catastrophic coverage, available in the individual market through the Exchange in the State in the county in which the individual resides to determine whether coverage exceeds the affordability threshold specified in section 5000A(e)(1) of the Code; and

* * * * *

■ 24. Section 155.610 is amended by revising paragraph (h)(2) to read as follows:

§ 155.610 Eligibility process for exemptions.

* * * * *

(h) * * *

(2) The Exchange will only accept an application for an exemption described in § 155.605(d)(1) during one of the 3 calendar years after the month or months during which the applicant attests that the hardship occurred.

* * * * *

■ 25. Section 155.700 is amended by revising paragraph (a) to read as follows:

§ 155.700 Standards for the establishment of a SHOP.

(a) *General requirement.* (1) For plan years beginning before January 1, 2018, an Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers and facilitate the enrollment of qualified employees into qualified health plans.

(2) For plan years beginning on or after January 1, 2018, an Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers in facilitating the enrollment of their employees in qualified health plans.

* * * * *

■ 26. Section 155.705 is amended by revising the section heading and adding paragraph (e) to read as follows:

§ 155.705 Functions of a SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(e) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.706 is applicable for plan years beginning on or after January 1, 2018.

■ 27. Section 155.706 is added to read as follows:

§ 155.706 Functions of a SHOP for plan years beginning on or after January 1, 2018.

(a) *Exchange functions that apply to SHOP.* The SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, K, and M of this part, except:

(1) Requirements related to individual eligibility determinations in subpart D of this part;

(2) Requirements related to enrollment of qualified individuals described in subpart E of this part;

(3) The requirement to issue certificates of exemption in accordance with § 155.200(b); and

(4) Requirements related to the payment of premiums by individuals, Indian tribes, tribal organizations and urban Indian organizations under § 155.240.

(b) *Unique functions of a SHOP.* The SHOP must also provide the following unique functions:

(1) *Enrollment and eligibility functions.* The SHOP must adhere to the requirements outlined in subpart H.

(2) *Employer choice requirements.* The SHOP must allow a qualified employer to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, in which all QHPs within that level are made available to the qualified employees of the employer.

(3) *SHOP options with respect to employer choice requirements.* (i) A SHOP:

(A) Must allow an employer to make available to qualified employees all QHPs at the level of coverage selected by the employer as described in paragraph (b)(2) of this section, and

(B) May allow an employer to make one or more QHPs available to qualified employees by a method other than the method described in paragraph (b)(2) of this section.

(ii) A Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make QHPs available to qualified employees:

(A) The employer may choose a level of coverage as described in paragraph (b)(2) of this section, or

(B) The employer may choose a single QHP.

(iii) A SHOP may, and a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make stand-alone dental plans available to qualified employees:

(A) The employer may choose to make available a single stand-alone dental plan.

(B) The employer may choose to make available all stand-alone dental plans offered through a SHOP.

(iv) A SHOP may also provide a qualified employer with a choice of a third method to make QHPs available to qualified employees by offering its qualified employees a choice of all QHPs offered through the SHOP by a single issuer across all available levels of coverage, as described in section 1302(d)(1) of the Affordable Care Act and implemented in § 156.140(b) of this subchapter. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(v) A SHOP may also provide a qualified employer with a choice of a third method to make stand-alone dental plans available to qualified employees by offering its qualified employees a choice of all stand-alone dental plans offered through the SHOP by a single issuer. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(vi) States operating a State Exchange utilizing the Federal platform for SHOP enrollment functions will have the same employer choice models available as States with a Federally-facilitated SHOP, except that a State with a State Exchange utilizing the Federal platform for SHOP enrollment functions may decide against offering the employer choice models specified in paragraphs (b)(3)(iv) and (v) of this section in that State, provided that the State notifies HHS of that decision in advance of the annual QHP certification application deadline, by a date to be established by HHS.

(4) *Continuation of Coverage.* The SHOP may, upon an election by a qualified employer, enter into an agreement with a qualified employer to facilitate the administration of continuation coverage by collecting premiums for continuation coverage enrolled in through the SHOP directly from a person enrolled in continuation coverage through the SHOP consistent with applicable law and the terms of the group health plan, and remitting

premium payments for this coverage to QHP issuers.

(5) *QHP Certification.* With respect to certification of QHPs in the small group market, the SHOP must ensure each QHP meets the requirements specified in § 156.285 of this subchapter.

(6) *Rates and rate changes.* The SHOP must—

(i) Require all QHP issuers to make any change to rates at a uniform time that is no more frequently than quarterly.

(A) In a Federally-facilitated SHOP, rates may be updated quarterly with effective dates of January 1, April 1, July 1, or October 1 of each calendar year. The updated rates must be submitted to HHS at least 60 days in advance of the effective date of the rates.

(B) [Reserved]

(ii) Prohibit all QHP issuers from varying rates for a qualified employer during the employer's plan year.

(7) *QHP availability in merged markets.* If a State merges the individual market and the small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, the SHOP may permit employer groups to enroll in any QHP meeting level of coverage requirements described in section 1302(d) of the Affordable Care Act.

(8) *QHP availability in unmerged markets.* If a State does not merge the individual and small group market risk pools, the SHOP must permit employer groups to enroll only in QHPs in the small group market.

(9) *SHOP expansion to large group market.* If a State elects to expand the SHOP to the large group market, a SHOP must allow issuers of health insurance coverage in the large group market in the State to offer QHPs in such market through a SHOP beginning in 2017 provided that a large employer meets the qualified employer requirements other than that it be a small employer.

(10) *Participation rules.* Subject to § 147.104 of this subchapter, the SHOP may authorize a uniform group participation rate for the offering of health insurance coverage in the SHOP, which must be a single, uniform rate that applies to all groups and issuers in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(i) Subject to § 147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of full-time employees accepting coverage offered by a qualified employer plus the number of full-time employees who, at the time the employer submits the SHOP group enrollment, are enrolled in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid, or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage.

(ii) Notwithstanding paragraphs (b)(10)(i) of this section, a Federally-facilitated SHOP may utilize a different minimum participation rate in a State if there is evidence that a State law sets a minimum participation rate or that a higher or lower minimum participation rate is customarily used by the majority of QHP issuers in that State for products in the State's small group market outside the SHOP.

(11) *Premium calculator.* In the SHOP, the premium calculator described in § 155.205(b)(6) must facilitate the comparison of available QHPs.

(c) *Coordination with individual market Exchange for eligibility determinations.* A SHOP that collects employee eligibility or enrollment data must provide data related to eligibility and enrollment of a qualified employee to the individual market Exchange that corresponds to the service area of the SHOP, unless the SHOP is operated pursuant to § 155.100(a)(2).

(d) *Duties of Navigators in the SHOP.* In States that have elected to operate only a SHOP pursuant to § 155.100(a)(2), at State option and if State law permits the Navigator duties described in § 155.210(e)(3) and (4) may be fulfilled through referrals to agents and brokers.

(e) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 28. Section 155.715 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 155.715 Eligibility determination process for SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.716 is applicable for plan years beginning on or after January 1, 2018.

■ 29. Section 155.716 is added to read as follows:

§ 155.716 Eligibility determination process for SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirement.* The SHOP must determine whether an employer requesting a determination of eligibility to participate in a SHOP is eligible in accordance with the requirements of § 155.710.

(b) *Applications.* The SHOP must accept a SHOP single employer application form from employers, in accordance with the relevant standards of § 155.730.

(c) *Verification of eligibility.* For the purpose of verifying employer eligibility, the SHOP—

(1) May establish, in addition to or in lieu of reliance on the application, additional methods to verify the information provided by the applicant on the applicable application;

(2) Must collect only the minimum information necessary for verification of eligibility in accordance with the eligibility standards described in § 155.710; and

(3) May not perform individual market Exchange eligibility determinations or verifications described in subpart D of this part.

(d) *Eligibility adjustment period.* When the information submitted on the SHOP single employer application is inconsistent with information collected from third-party data sources through the verification process described in paragraph (c)(1) of this section or otherwise received by the SHOP, the SHOP must—

(1) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(2) Notify the employer of the inconsistency;

(3) Provide the employer with a period of 30 days from the date on which the notice described in paragraph (d)(2) of this section is sent to the employer to either present satisfactory documentary evidence to support the employer's application, or resolve the inconsistency; and

(4) If, after the 30-day period described in paragraph (d)(2) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must—

(i) Notify the employer of its denial or termination of eligibility in accordance with paragraph (e) of this section and of the employer's right to appeal such determination; and

(ii) If the employer was enrolled pending the confirmation or verification of eligibility information, discontinue the employer's participation in the

SHOP at the end of the month following the month in which the notice is sent.

(e) *Notification of employer eligibility.* The SHOP must provide an employer requesting eligibility to purchase coverage through the SHOP with a notice of approval or denial or termination of eligibility and the employer's right to appeal such eligibility determination.

(f) *Validity of Eligibility Determination.* An employer's determination of eligibility to participate in SHOP remains valid until the employer makes a change that could end its eligibility under § 155.710(b) or withdraws from participation in the SHOP.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 30. Section 155.720 is amended by revising the section heading and adding paragraph (j) to read as follows:

§ 155.720 Enrollment of employees into QHPs under SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(j) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.721 is applicable for plan years beginning on or after January 1, 2018.

■ 31. Section 155.721 is added to read as follows:

§ 155.721 Record retention and IRS Reporting for plan years beginning on or after January 1, 2018.

(a) *Records.* The SHOP must receive and maintain for at least 10 years records of qualified employers participating in the SHOP.

(b) *Reporting requirement for tax administration purposes.* The SHOP must, at the request of the IRS, report information to the IRS about employer eligibility to participate in SHOP coverage.

(c) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 32. Section 155.725 is amended by revising the section heading and adding paragraph (l) to read as follows:

§ 155.725 Enrollment periods under SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(l) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.726 is applicable for plan years beginning on or after January 1, 2018.

■ 33. Section 155.726 is added to read as follows:

§ 155.726 Enrollment periods under SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* The SHOP must ensure that issuers offering QHPs through the SHOP adhere to applicable enrollment periods, including special enrollment periods.

(b) *Rolling enrollment in the SHOP.* The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage, unless the plan is issued in a State that has elected to merge its individual and small group risk pools under section 1312(c)(3) of the Affordable Care Act, in which case the plan year will end on December 31 of the calendar year in which coverage first became effective.

(c) *Special enrollment periods.* (1) The SHOP must ensure that issuers offering QHPs through the SHOP provide special enrollment periods consistent with the section, during which certain qualified employees or dependents of qualified employees may enroll in QHPs and enrollees may change QHPs.

(2) The SHOP must ensure that issuers offering QHPs through a SHOP provide a special enrollment period for a qualified employee or a dependent of a qualified employee who;

(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);

(ii) Loses eligibility for coverage under a Medicaid plan under title XIX of the Social Security Act or a State child health plan under title XXI of the Social Security Act; or

(iii) Becomes eligible for assistance, with respect to coverage under a SHOP, under such Medicaid plan or a State child health plan (including any waiver or demonstration project conducted under or in relation to such a plan).

(3) A qualified employee or dependent of a qualified employee who experiences a qualifying event described in paragraph (j)(2) of this section has:

(i) Thirty (30) days from the date of a triggering event described in paragraph (c)(2)(i) of this section to select a QHP through the SHOP; and

(ii) Sixty (60) days from the date of a triggering event described in paragraph (c)(2)(ii) or (iii) of this section to select a QHP through the SHOP;

(4) A dependent of a qualified employee is not eligible for a special enrollment period if the employer does not extend the offer of coverage to dependents.

(5) The effective dates of coverage for special enrollment periods are determined using the provisions of § 155.420(b).

(6) Loss of minimum essential coverage is determined using the provisions of § 155.420(e).

(d) *Limitation.* Qualified employees will not be able to enroll unless the employer group meets any applicable minimum participation rate implemented under § 155.706(b)(10).

(e) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 34. Section 155.730 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 155.730 Application standards for SHOP for plan year beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.731 is applicable for plan years beginning on or after January 1, 2018.

■ 35. Section 155.731 is added to read as follows:

§ 155.731 Application standards for SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* Application forms used by the SHOP must meet the requirements set forth in this section.

(b) *Single employer application.* The SHOP must use a single application to determine employer eligibility. Such application must collect the following—

(1) Employer name and address of employer's locations;

(2) Information sufficient to confirm the employer is a small employer;

(3) Employer Identification Number (EIN); and

(4) Information sufficient to confirm that the employer is offering, at a minimum, all full-time employees coverage in a QHP through a SHOP.

(c) *Model application.* The SHOP may use the model single employer application provided by HHS.

(d) *Alternative employer application.* The SHOP may use an alternative application if such application is approved by HHS and collects the information described in paragraph (b).

(e) *Filing.* The SHOP must:

(1) Accept applications from SHOP application filers; and

(2) Provide the tools to file an employer eligibility application via an internet website.

(f) *Additional safeguards.* (1) The SHOP may not provide to the employer any information collected on an

employee application with respect to spouses or dependents other than the name, address, and birth date of the spouse or dependent.

(2) The SHOP is not permitted to collect information on the single employer or on an employee application unless that information is necessary to determine SHOP eligibility or effectuate enrollment through the SHOP.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

■ 36. Section 155.735 is amended by revising the section heading and adding paragraph (h) to read as follows:

§ 155.735 Termination of SHOP enrollment or coverage for plan years beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning before January 1, 2018.

■ 37. Section 155.740 is amended by revising the section heading and adding paragraph (p) to read as follows:

§ 155.740 SHOP employer and employee eligibility appeals requirements for plan years beginning prior to January 1, 2018.

* * * * *

(p) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.741 is applicable for plan years beginning on or after January 1, 2018.

■ 38. Section 155.741 is added to subpart H to read as follows:

§ 155.741 SHOP employer and employee eligibility appeals requirements for plan year beginning on or after January 1, 2018.

(a) *Definitions.* The definitions in §§ 155.20, 155.300, and 155.500 apply to this section.

(b) *General requirements.* (1) A State, establishing an Exchange that provides for the establishment of a SHOP pursuant to § 155.100 must provide an eligibility appeals process for the SHOP. Where a State has not established an Exchange that provides for the establishment of a SHOP pursuant to § 155.100, HHS will provide an eligibility appeals process for the SHOP that meets the requirements of this section and the requirements in paragraph (b)(2) of this section.

(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).

(c) *Employer right to appeal.* An employer may appeal—

(1) A notice of denial or termination of eligibility under § 155.716(e); or

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with § 155.716(e).

(d) *Appeals notice requirement.* Notices of the right to appeal a denial of eligibility under § 155.716(e) must be written and include—

(1) The reason for the denial or termination of eligibility, including a citation to the applicable regulations; and

(2) The procedure by which the employer may request an appeal of the denial or termination of eligibility.

(e) *Appeal request.* The SHOP and appeals entity must—

(1) Allow an employer to request an appeal within 90 days from the date of the notice of denial or termination of eligibility to—

(i) The SHOP or the appeals entity; or

(ii) HHS, if no State Exchange that provides for establishment of a SHOP has been established;

(2) Accept appeal requests submitted through any of the methods described in § 155.520(a)(1);

(3) Comply with the requirements of § 155.520(a)(2) and (3); and

(4) Consider an appeal request valid if it is submitted in accordance with paragraph (e)(1) of this section.

(f) *Notice of appeal request.* (1) Upon receipt of a valid appeal request, the appeals entity must—

(i) Send timely acknowledgement to the employer of the receipt of the appeal request, including—

(A) An explanation of the appeals process; and

(B) Instructions for submitting additional evidence for consideration by the appeals entity.

(ii) Promptly notify the SHOP of the appeal, if the appeal request was not initially made to the SHOP.

(2) Upon receipt of an appeal request that is not valid because it fails to meet the requirements of this section, the appeals entity must—

(i) Promptly and without undue delay, send written notice to the employer that is appealing that—

(A) The appeal request has not been accepted,

(B) The nature of the defect in the appeal request; and

(C) An explanation that the employer may cure the defect and resubmit the appeal request if it meets the timeliness requirements of paragraph (e) of this section, or within a reasonable timeframe established by the appeals entity.

(ii) Treat as valid an amended appeal request that meets the requirements of this section.

(g) *Transmittal and receipt of records.* (1) Upon receipt of a valid appeal request under this section, or upon receipt of the notice under paragraph (f)(2) of this section, the SHOP must promptly transmit, via secure electronic interface, to the appeals entity—

(i) The appeal request, if the appeal request was initially made to the SHOP; and

(ii) The eligibility record of the employer that is appealing.

(2) The appeals entity must promptly confirm receipt of records transmitted pursuant to paragraph (g)(1) of this section to the SHOP that transmitted the records.

(h) *Dismissal of appeal.* The appeals entity—

(1) Must dismiss an appeal if the employer that is appealing—

(i) Withdraws the request in accordance with the standards set forth in § 155.530(a)(1); or

(ii) Fails to submit an appeal request meeting the standards specified in paragraph (e) of this section.

(2) Must provide timely notice to the employer that is appealing of the dismissal of the appeal request, including the reason for dismissal, and must notify the SHOP of the dismissal.

(3) May vacate a dismissal if the employer makes a written request within 30 days of the date of the notice of dismissal showing good cause why the dismissal should be vacated.

(i) *Procedural rights of the employer.* The appeals entity must provide the employer the opportunity to submit relevant evidence for review of the eligibility determination.

(j) *Adjudication of SHOP appeals.* SHOP appeals must—

(1) Comply with the standards set forth in § 155.555(i)(1) and (3); and

(2) Consider the information used to determine the employer's eligibility as well as any additional relevant evidence submitted during the course of the appeal by the employer or employee.

(k) *Appeal decisions.* Appeal decisions must—

(1) Be based solely on—

(i) The evidence referenced in paragraph (j)(2) of this section;

(ii) The eligibility requirements for the SHOP under § 155.710(b), as applicable.

(2) Comply with the standards set forth in § 155.545(a)(2) through (5)

(3) Be effective as follows:

(i) If an employer is found eligible under the decision, then at the employer's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made retroactive to the effective date of coverage or enrollment through the

SHOP that the employer would have had if the employer had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(ii) If the employer is found ineligible under the decision, then the appeal decision is effective as of the date of the notice of the appeal decision.

(l) *Notice of appeal decision.* The appeals entity must issue written notice of the appeal decision to the employer and to the SHOP within 90 days of the date the appeal request is received.

(m) *Implementation of SHOP appeal decisions.* The SHOP must promptly implement the appeal decision upon receiving the notice under paragraph (l) of this section.

(n) *Appeal record.* Subject to the requirements of § 155.550, the appeal record must be accessible to the employer in a convenient format and at a convenient time.

(o) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 39. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 40. Section 156.100 is amended by revising the section heading and the introductory text and by adding paragraph (d) to read as follows:

§ 156.100 State selection of benchmark plan for plan years beginning prior to January 1, 2020.

For plan years beginning before January 1, 2020, each State may identify a base-benchmark plan according to the selection criteria described below:

* * * * *

(d) *Applicability date:* For plan years beginning on or after January 1, 2020, § 156.111 applies in place of this section.

■ 41. Section 156.111 is added to Subpart B to read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

(a) Subject to paragraphs (b), (c), (d) and (e) of this section, for plan years beginning on or after January 1, 2020, a State may change its EHB-benchmark plan by:

(1) Selecting the EHB-benchmark plan that another State used for the 2017 plan year under § 156.100 and § 156.110;

(2) Replacing one or more categories of EHBs established at § 156.110(a) in the State's EHB-benchmark plan used for the 2017 plan year with the same category or categories of EHB from the EHB-benchmark plan that another State used for the 2017 plan year under § 156.100 and § 156.110; or

(3) Otherwise selecting a set of benefits that would become the State's EHB-benchmark plan.

(b) A State's EHB-benchmark plan must:

(1) *EHB coverage.* Provide coverage of items and services for at least the categories of benefits at § 156.110(a), including an appropriate balance of coverage for these categories of benefits.

(2) *Scope of benefits.* (i) Provide a scope of benefits equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, defined as either:

(A) One of the selecting State's 10 base-benchmark plan options established at § 156.100, and available for the selecting State's selection for the 2017 plan year; or

(B) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at § 144.103 of this subchapter, provided that:

(*1*) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(*2*) The plan provides minimum value, as defined under § 156.145;

(*3*) The benefits are not excepted benefits, as established under § 146.145(b), and § 148.220 of this subchapter; and

(*4*) The benefits in the plan are from a plan year beginning after December 31, 2013.

(ii) Not exceed the generosity of the most generous among a set of comparison plans, including:

(A) The State's EHB-benchmark plan used for the 2017 plan year, and

(B) Any of the State's base-benchmark plan options for the 2017 plan year described in § 156.100(a)(1), supplemented as necessary under § 156.110.

(iii) Not have benefits unduly weighted towards any of the categories of benefits at § 156.110(a);

(iv) Provide benefits for diverse segments of the population, including women, children, persons with disabilities, and other groups; and

(v) Not include discriminatory benefit designs that contravene the non-discrimination standards defined in § 156.125.

(c) The State must provide reasonable public notice and an opportunity for public comment on the State's selection of an EHB-benchmark plan that includes posting a notice on its opportunity for public comment with associated information on a relevant State website.

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by a date to be determined by HHS for each applicable plan year.

(1) If the State does not make a selection by the annual selection date, or its benchmark plan selection does not meet the requirements of this section and section 1302 of the PPACA, the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year.

(2) [Reserved]

(e) A State changing its EHB-benchmark plan under this section must submit documents in a format and manner specified by HHS by a date determined by HHS. These must include:

(1) A document confirming that the State's EHB-benchmark plan definition complies with the requirements under paragraphs (a), (b) and (c) of this section, including information on which selection option under paragraph (a) of this section the State is using, and whether the State is using another State's EHB-benchmark plan;

(2) An actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms:

(i) That the State's EHB-benchmark plan provides a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a), the scope of benefits provided under a typical employer plan, as defined at (b)(2)(i) of this section; and

(ii) That the State's EHB-benchmark plan does not exceed the generosity of the most generous among the plans listed in paragraphs (b)(2)(ii)(A) and (B) of this section.

(3) The State's EHB-benchmark plan document that reflects the benefits and limitations, including medical management requirements, a schedule of benefits and, if the State is selecting its EHB-benchmark plan using the

option in paragraph (a)(3) of this section, a formulary drug list in a format and manner specified by HHS; and

(4) Other documentation specified by HHS, which is necessary to operationalize the State's EHB-benchmark plan.

■ 42. Section 156.115 is amended by revising paragraph (b) to read as follows:

§ 156.115 Provision of EHB.

* * * * *

(b) An issuer of a plan offering EHB may substitute benefits for those provided in the EHB-benchmark plan under the following conditions—

(1) The issuer substitutes a benefit that:

(i) Is actuarially equivalent to the benefit that is being replaced as determined in paragraph (b)(4) of this section; and

(ii) Is not a prescription drug benefit.

(2) An issuer may substitute a benefit under this paragraph:

(i) Within the same EHB category, unless prohibited by applicable State requirements; and

(ii) For plan years beginning on or after January 1, 2020, between EHB categories, if the State in which the plan will be offered has notified HHS that substitution between EHB categories is permitted in the State.

(3) The plan that includes substituted benefits must:

(i) Continue to comply with the requirements of paragraph (a) of this section, including by providing benefits that are substantially equal to the EHB-benchmark plan;

(ii) Provide an appropriate balance among the EHB categories such that benefits are not unduly weighted toward any category; and

(iii) Provide benefits for diverse segments of the population.

(4) The issuer submits to the State evidence of actuarial equivalence that is:

(i) Certified by a member of the American Academy of Actuaries;

(ii) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(iii) Based on a standardized plan population; and

(iv) Determined without taking cost-sharing into account.

* * * * *

■ 43. Section 156.150 is amended by revising paragraph (b) to read as follows:

§ 156.150 Application to stand-alone dental plans inside the Exchange.

* * * * *

(b) *Calculation of AV.* A stand-alone dental plan:

(1) May not use the AV calculator in § 156.135; and

(2) Must have the plan's actuarial value of coverage for pediatric dental essential health benefits certified by a member of the American Academy of Actuaries using generally accepted actuarial principles and reported to the Exchange.

* * * * *

■ 44. Section 156.200 is amended by revising paragraph (b)(2) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(b) * * *

(2) Comply with Exchange processes, procedures, and requirements set forth in accordance with subpart K of part 155 of this subchapter and, in the small group market, §§ 155.705 and 155.706 of this subchapter;

* * * * *

■ 45. Section 156.285 is amended by revising the section heading and adding paragraph (f) to read as follows:

§ 156.285 Additional standards specific to SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(f) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Additional standards specific to SHOP for plan years beginning on or after January 1, 2018 are in § 156.286.

■ 46. Section 156.286 is added to read as follows:

§ 156.286 Additional standards specific to SHOP for plan years beginning on or after January 1, 2018.

(a) *SHOP rating and premium payment requirements.* QHP issuers offering a QHP through a SHOP must:

(1) Accept payment from a qualified employer or an enrollee, or a SHOP on behalf of a qualified employer or enrollee, in accordance with applicable SHOP requirements.

(2) Adhere to the SHOP timeline for rate setting as established in § 155.706(b)(6) of this subchapter;

(3) Charge the same contract rate for a plan year; and

(4) Adhere to the premium rating standards described in § 147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market.

(b) *Enrollment periods and processes for the SHOP.* QHP issuers offering a QHP through the SHOP must adhere to enrollment periods and processes established by the SHOP, consistent with § 155.726 of this subchapter, and establish a uniform enrollment timeline and process for enrolling qualified employers and employer group members.

(c) *Enrollment process for the SHOP.* A QHP issuer offering a QHP through the SHOP must:

(1) Provide new enrollees with the enrollment information package as described in § 156.265(e); and

(2) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(d) *Participation rules.* QHP issuers offering a QHP through the SHOP may impose group participation rules for the offering of health insurance coverage in connection with a QHP only if and to the extent authorized by the SHOP in accordance with § 155.706 of this subchapter.

(e) *Employer choice.* QHP issuers offering a QHP through the SHOP must accept enrollments from groups in accordance with the employer choice policies applicable to the SHOP under § 155.706(b)(3) of this subchapter.

(f) *Identification of SHOP enrollments.* QHP issuers offering a QHP through the SHOP must use a uniform enrollment form, maintain processes sufficient to identify whether a group market enrollment is an enrollment through the SHOP, and maintain records of SHOP enrollments for a period of 10 years following the enrollment.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

§ 156.298 [Removed]

■ 47. Section 156.298 is removed.

■ 48. Section 156.340 is amended by revising paragraph (a)(2) to read as follows:

§ 156.340 Standards for downstream and delegated entities.

(a) * * *

(2) Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, § 155.705 and § 155.706 of this subchapter;

* * * * *

■ 49. Section 156.350 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) * * *

(1) Section 156.285(a)(4)(ii) regarding the premiums for plans offered on the SHOP, for plan years beginning prior to January 1, 2018;

(2) Section 156.285(c)(5) and (c)(8)(iii) regarding the enrollment process for

SHOP, for plan years beginning prior to January 1, 2018; and

* * * * *

■ 50. Section 156.1230 is amended by revising paragraph (b)(2) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(2) The QHP issuer must engage a third-party entity in accordance with § 155.221 of this subchapter to demonstrate operational readiness and compliance with applicable requirements prior to the QHP issuer's internet website being used to complete a QHP selection.

* * * * *

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 the section heading and adding paragraph (h) to read as follows:

§ 157.205 Qualified employer participation process in a SHOP for plan years beginning prior to January 1, 2018.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 157.206 is applicable for plan years beginning on or after January 1, 2018.

■ 53. Section 157.206 is added to read as follows:

§ 157.206 Qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* When joining the SHOP, a qualified employer must comply with the requirements, processes, and timelines set forth by this part and must remain in compliance for the duration of the employer's participation in the SHOP.

(b) *Selecting QHPs.* During an election period, a qualified employer may make coverage in a QHP available through the SHOP in accordance with the processes developed by the SHOP in accordance with § 155.706 of this subchapter.

(c) *Information dissemination to employees.* A qualified employer participating in the SHOP must disseminate information to its qualified employees about the process to enroll in a QHP through the SHOP.

(d) *Employees hired outside of the initial or annual open enrollment period.* Qualified employers must provide employees hired outside of the initial or annual open enrollment period with information about the enrollment process.

(e) *Participation in the SHOP and termination of coverage or enrollment through the SHOP.* (1) Changes affecting participation. Employers must submit a new single employer application to the SHOP or withdraw from participating in the SHOP if the employer makes a change that could end its eligibility under § 155.710 of this subchapter.

(2) If an employer receives a determination of ineligibility to participate in the SHOP or the SHOP terminates its eligibility to participate in the SHOP, unless the SHOP notifies the issuer or issuers of the determination of ineligibility or termination of eligibility, the employer must notify the issuer or issuers of QHPs in which their group members are enrolled in coverage of its ineligibility or termination of eligibility within 5 business days of the end of any applicable appeal process under § 155.741 of this subchapter, which could include when the time to file an appeal lapses without an appeal being filed, when the appeal is rejected or dismissed, or when the appeal process concludes with an adjudication by the appeals entity, as applicable.

(3) Employers must promptly notify the issuer or issuers of QHPs in which their group members are enrolled in coverage if it wishes to terminate coverage or enrollment through the SHOP, unless the SHOP notifies the issuer or issuers.

(f) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 54. 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.

■ 55. Section 158.170 is amended by revising paragraph (b) introductory text to read as follows:

§ 158.170 Allocation of expenses.

* * * * *

(b) *Description of the methods used to allocate expenses.* The report required in § 158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses (unless the report utilizes the percentage of premium option described in § 158.221(b)(8), in which case the allocation method description should state so), Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

* * * * *

■ 56. Section 158.221 is amended by adding paragraph (b)(8) to read as follows:

§ 158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *

(b) * * *

(8) Beginning with the 2017 MLR reporting year, an issuer has the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. If an issuer chooses this method of reporting, it must apply it for a minimum of 3 consecutive MLR reporting years and for all of its individual, small group, and large group markets; and all affiliated issuers must choose the same reporting method.

* * * * *

■ 57. Section 158.301 is revised to read as follows:

§ 158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section 2791 of the PHS Act, for a given MLR reporting year if, in the Secretary's discretion, the Secretary determines that there is a reasonable likelihood that an adjustment to the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act will help stabilize the individual market in that State.

■ 58. Section 158.321 is revised to read as follows:

§ 158.321 Information regarding the State's individual health insurance market.

(a) Subject to § 158.320, the State must provide, for each issuer who actively offers coverage in the individual market in the State, the following information, in accordance with paragraph (b) of this section, for

the preceding calendar year and, at the State's option, for the current year:

(1) Total earned premium and incurred claims;

(2) Total number of enrollees (life-years and covered lives);

(3) Total agents' and brokers' commission expenses;

(4) Net underwriting gain;

(5) Risk-based capital level; and

(6) Whether the issuer has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

(b) The information required in paragraphs (a)(1) through (4) and (6) of this section must be provided separately for the issuer's individual market plans grouped by the following categories, as applicable: On-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage. The information required in paragraph (a)(5) of this section must be provided at the issuer level.

(c) The State must also provide information regarding whether any issuer other than those described in paragraph (a) of this section has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

■ 59. Section 158.322 is revised to read as follows:

§ 158.322 Proposal for adjusted medical loss ratio.

A State must provide its own proposal as to the adjustment it seeks to the MLR standard. This proposal must include an explanation of how an adjustment to the MLR standard for the State's individual market will help stabilize the State's individual market.

■ 60. Section 158.330 is revised to read as follows:

§ 158.330 Criteria for assessing request for adjustment to the medical loss ratio.

The Secretary may consider the following criteria in assessing whether an adjustment to the 80 percent MLR standard, as calculated in accordance with this subpart, would be reasonably likely to help stabilize the individual market in a State that has requested such adjustment:

(a) The number and financial performance (based on data provided by a State under § 158.321) of issuers actively offering individual health insurance coverage on- and off-Exchange, grandfathered health plans as defined in § 147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage; the number of issuers reasonably likely to cease or begin offering individual market coverage in the State; and the likelihood that an adjustment to the 80 percent MLR standard could help increase competition in the individual market in the State, including in underserved areas.

(b) Whether an adjustment to the 80 percent MLR standard for the individual market may improve consumers' access to agents and brokers.

(c) The capacity of any new issuers or issuers remaining in the individual market to write additional business in the event one or more issuers were to cease offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(d) The impact on premiums charged, and on benefits and cost sharing provided, to consumers by issuers remaining in or entering the individual market in the event one or more issuers were to cease or begin offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(e) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

■ 61. Section 158.341 is revised to read as follows:

§ 158.341 Treatment as a public document.

A State's request for an adjustment to the MLR standard, and all information submitted as part of its request, will be treated as a public document. Instructions for how to access documents related to a State's request for an adjustment to the MLR standard will be made available on the Secretary's website.

■ 62. Section 158.350 is revised to read as follows:

§ 158.350 Subsequent requests for adjustment to the medical loss ratio.

A State that has made a previous request for an adjustment to the MLR standard must, in addition to the other information required by this subpart, submit information as to what steps the State has taken since its prior requests, if any, to improve the stability of the State's individual market.

Dated: March 6, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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