

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146, 147, 148, 153, 155, and 156

[CMS-9926-F]

RIN 0938-AT37

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

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 (FFE) and State-based Exchanges on the Federal Platform (SBE-FPs). It finalizes changes that will allow greater flexibility related to the duties and training requirements for the Navigator program and changes that will provide greater flexibility for direct enrollment entities, while strengthening program integrity oversight over those entities. It finalizes a change intended to reduce the costs of prescription drugs. This final rule also includes changes to Exchange standards related to eligibility and enrollment; exemptions; and other related topics.

DATES: These regulations are effective on June 24, 2019.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu, (301) 492-4305, Kiahana Brooks, (301) 492-5229, Ken Buerger, (410) 786-1190, or Abigail Walker, (410) 786-1725, for general information.

David Mlawsky, (410) 786-6851, for matters related to guaranteed renewability.

Avareena Cropper, (410) 786-3794, for matters related to sequestration.

Allison Yadsco, (410) 786-1740, for matters related to risk adjustment.

Jacalyn Boyce, (301) 492-5122, for matters related to Federally-facilitated Exchange and State-based Exchange on the Federal Platform user fees.

Abigail Walker, (410) 786-1725, Alper Ozinal, (301) 492-4178, Allison Yadsco, (410) 786-1740, or Adam Shaw, (410) 786-1091, for matters related to risk adjustment data validation.

Ken Buerger, (410) 786-1190, or LeAnn Brodhead, (410) 786-3943, for matters related to the opioid crisis.

Amir Al-Kourainy, (301) 492-5210, for matters related to Navigators.

Carly Rhyne, (301) 492-4188, for matters related to special enrollment periods.

Amanda Brander, (202) 690-7892, for matters related to exemptions.

Daniel Brown, (434) 995-5886, for matters related to direct enrollment.

Leigha Basini, (301) 492-4380, for matters related to health insurance issuer drug policy, essential health benefits, and qualified health plan certification requirements.

Abigail Walker, (410) 786-1725, for matters related to the required contribution percentage, cost-sharing parameters, and the premium adjustment percentage.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
- II. Background
 - A. Legislative and Regulatory Overview
 - B. Stakeholder Consultation and Input
 - C. Structure of Final Rule
- III. Provisions of the Final Regulations and Analysis and Responses to Public Comments
 - A. Part 146—Requirements for the Group Health Insurance Market
 - B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets
 - C. Part 148—Requirements for the Individual Health Insurance Market
 - D. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act
 - E. Part 155—Exchange Establishment Standards and Other Related Standards under the Affordable Care Act
 - F. Part 156—Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges
- IV. Collection of Information Requirements
 - A. Wage Estimates
 - B. ICRs Regarding Risk Adjustment Data Validation Exemptions
 - C. ICRs Regarding Agent or Broker Termination and Web Broker Data Collection
 - D. ICRs Regarding Direct Enrollment Entity Standardized Disclaimer
 - E. ICRs Regarding Special Enrollment Periods
 - F. ICRs Regarding Eligibility Standards for Exemptions
 - G. Summary of Annual Burden Estimates for Requirements
 - H. 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
- J. Conclusion

I. Executive Summary

American Health Benefit Exchanges, or “Exchanges” are entities established under the Patient Protection and Affordable Care Act¹ (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 to reduce their costs for health insurance premiums and to 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.

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. This rule will, within the limitations of the current statute, reduce fiscal and regulatory burdens across different program areas and provide stakeholders with greater flexibility.

Over time, issuer market exits and increasing insurance rates have threatened the stability of the individual and small group market Exchanges in many geographic areas. These dynamics have put coverage out of reach for many, notably those consumers enrolling outside of the Exchanges, who do not benefit from the PPACA’s advance payments of the premium tax credit (APTC).

In previous rulemaking, we have established provisions and parameters to implement many PPACA requirements and programs. In this rule, we amend these provisions and parameters, with a focus on maintaining a stable regulatory environment to provide issuers with greater

¹ The PPACA (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 PPACA, 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”.

predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs and providing states with additional flexibilities, reducing unnecessary regulatory burdens on stakeholders, empowering consumers, and improving affordability.

Risk adjustment continues to be a core program in the individual and small group markets both on and off the Exchanges, and we are finalizing recalibrated parameters for the HHS-operated risk adjustment methodology. We are finalizing several changes related to the risk adjustment data validation program that are intended to ensure the integrity of the results of risk adjustment, and others intended to alleviate issuer burden associated with complying with risk adjustment data validation requirements.

As we do every year in the HHS notice of benefit and payment parameters, we are finalizing updated parameters applicable in the individual and small group markets. We are finalizing the user fee rate for issuers participating on Federally-facilitated Exchanges (FTEs) and State-based Exchanges on the Federal platform (SBE-FPs) for 2020 to be 3.0 and 2.5 percent of premiums, respectively. These rates are a decrease from past years, which will increase affordability for consumers. We are finalizing updates to the premium adjustment percentage methodology and amount, and consequently the maximum annual limitations on cost sharing for the 2020 benefit year, including those for cost-sharing reduction plan variations.

We are finalizing changes to the requirements regarding Navigators to reduce burden, increase flexibility, and enable Exchanges to more easily and cost-effectively operate Navigator programs. Streamlining the Navigator training requirements and authorizing but not requiring assisters to provide certain types of assistance, including post-enrollment assistance, will allow assisters to allocate their resources in a manner that best meets community needs, consumer demands, and organizational resources.

We are finalizing a number of changes in this rule that are intended to reduce the burden for consumers by making it easier to enroll in affordable coverage through the Exchanges. First, we are finalizing a policy that would provide additional flexibility to those in need of a hardship exemption that currently must be obtained by filing an application with an Exchange, by expanding the types of hardship exemptions that consumers may claim for 2018 through the tax filing process.

Second, we believe consumers should have greater flexibility in how they shop for coverage, including the avenues through which they enroll in QHPs. As such, we have been working to expand opportunities for individuals to directly enroll in Exchange coverage through the websites of certain third parties, called direct enrollment entities, rather than having to visit *HealthCare.gov*. Third, we are finalizing several regulatory changes to streamline the regulatory requirements applicable to these direct enrollment entities. Fourth, we are finalizing a proposal to create a special enrollment period for off-Exchange enrollees who experience a decrease in household income and are determined to be eligible for APTC by the Exchange. This will allow enrollees to enroll in a more affordable on-Exchange product when a consumer's household income decreases mid-year.

We requested comment on automatic re-enrollment processes and capabilities, as well as additional policies or program measures that would reduce eligibility errors and potential government misspending for potential action in future rulemaking applicable not sooner than plan year 2021.

In the proposed rule, we discussed why we believe increased transparency is a critical component of a consumer driven health care system, and expressed our interest to receive comments discussing ways to provide consumers with greater transparency with regards to their own health care data, QHP offerings on the FTEs, and the cost of health care services. We continue to believe that when consumers have access to relevant, meaningful, and consumer-friendly information, they are empowered to make more informed decisions with regards to their care.

The proposed rule discussed a future opportunity for public input on ways to increase the interoperability of patient-mediated health care data across health care programs, including in coverage purchased through the Exchanges. To that end, in the March 4, 2019 **Federal Register**, we published the "Interoperability and Patient Access Proposed Rule" with a 60-day public comment period. The Interoperability and Patient Access Proposed Rule includes policy proposals to make certain health care data easily accessible through common technologies in a convenient, timely, and portable way. We encourage public input on that proposed rule.

Additionally, we sought comment on ways to further implement section 1311(e)(3) of the PPACA, as implemented by 45 CFR 156.220(d),

where a QHP issuer must make available the amount of enrollee cost sharing under the individual's plan or coverage for the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. We were particularly interested in input regarding what types of data will be most useful to improving consumers' abilities to make informed health care decisions, including decisions related to their coverage.

We also expressed our interest in ways to improve consumers' access to information about health care costs. We stated that we believe that consumers would benefit from a greater understanding of what their potential out-of-pocket costs would be for various services, based on which QHP they are enrolled in and which provider they see. We stated that we believe that such a policy would promote consumers' ability to shop for covered services, and to play a more active role in their health care.

We also are finalizing our proposal to create a limited data set file using masked enrollee-level data submitted to HHS from the External Data Gathering Environment (EDGE) servers for issuers of risk adjustment covered plans in the individual and small group (including merged) markets, with one modification: We will not make this limited data set available for public health or health care operations purposes. Thus, we are finalizing our proposal to make this file available to requestors who seek the data for research purposes only. In addition, we are finalizing our proposal to broaden the permissible HHS uses of the enrollee-level EDGE data currently submitted for purposes of risk adjustment. We believe this will increase understanding of these markets and contribute to greater transparency.

We sought comment on ways that we can promote the offering and take-up of high deductible health plans (HDHPs) that can be paired with health savings accounts (HSAs), which can serve as an effective and tax-advantageous method for certain consumers to manage their health care expenditures. We also sought comments for ways to increase the visibility of HSA-eligible HDHPs on *HealthCare.gov*.

In furtherance of the Administration's priority to reduce prescription drug costs and to align with the President's American Patients First blueprint, we proposed a series of changes regarding prescription drug benefits, to the extent permitted by applicable state law. These proposals included provisions that would allow issuers to adopt mid-year formulary changes to incentivize greater

enrollee use of lower-cost generic drugs and that would allow issuers to not count certain cost sharing toward the annual limitation on cost sharing if a consumer selects a brand drug when a medically appropriate generic drug is available. Based on issues raised by commenters, we are not finalizing these proposals. However, we are finalizing a change that would allow issuers and plans to exclude drug manufacturer coupons from counting toward the annual limitation on cost sharing when a medically appropriate generic drug is available. We expect this change to support issuers' and plans' ability to lower the cost of coverage and generate cost savings while also ensuring efficient use of federal funds and sufficient coverage for people with diverse health needs.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets, including a guaranteed renewability requirement in the individual, small group, and large group markets.

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 PHS Act relating to group health plans and health insurance issuers in the group and individual markets.

Section 1302 of the PPACA provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value 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,

adherence to the cost-sharing limits described in section 1302(c) of the PPACA, and meeting the actuarial value (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 requirement to cover 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 1311(d)(3)(B) of the PPACA permits a state, at its option, to require QHPs to cover benefits in addition to the EHB. This section also 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.

Section 1302(d) of the PPACA describes the various levels of coverage based on 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.²

Section 1311(d)(4)(B) of the PPACA requires an Exchange to provide for the operation of a toll-free telephone hotline to respond to requests for assistance.

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

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 premium tax credits and cost-sharing reductions 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 for, among other things, the establishment and operation of Exchanges.

Section 1311(c) of the PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(e)(1) of the PPACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the PPACA, and the Exchange determines that making the plan available through the Exchange is in the interests of individuals and employers in the state.

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. Office of Management and Budget (OMB) Circular A-25 establishes federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special

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

benefits derived from federal activities beyond those received by the general public.

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-than average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average 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 Internal Revenue Code (the Code), as added by section 1501(b) of the PPACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to \$0, effective for months beginning after December 31, 2018.³ Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals above the age of 30 qualify to enroll in catastrophic coverage under § 155.305(h).

The Protecting Affordable Coverage for Employees Act (Pub. L. 114–60, enacted on October 7, 2015) amended the definition of small employer in section 1304(b) of the PPACA and section 2791(e) of the PHS Act to mean, in connection with a group health plan for 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, for 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 Programs⁴

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 June 19, 2013 **Federal Register** (78 FR 37032), we proposed a modification to the HHS-operated methodology related to community rating states. In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the proposed modification to the HHS-operated methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 **Federal Register** (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743). In the May 27, 2014 **Federal Register** (79 FR 30240), the 2015 fiscal year sequestration rates for the risk adjustment and reinsurance programs were announced.

⁴ The term premium stabilization programs refers to the risk adjustment, risk corridors, and reinsurance programs established by the PPACA. See 42 U.S.C. 18061, 18062, and 18063.

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 the HHS 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).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining the benefit and payment parameters for the 2019 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology and amendments to the risk adjustment data validation process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930). We published a correction to the 2019 benefit year risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 **Federal Register** (83 FR 21925). On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional

³ Public Law 115–97, 131 Stat. 2054 (2017).

recalibration related to an update to the 2016 enrollee-level EDGE dataset.⁵

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and in the March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). This final rule sets forth additional explanation of the rationale supporting the use of the statewide average premium in the HHS-operated risk adjustment state payment transfer calculation for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. This final rule permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.⁶

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule seeking comment on adopting the 2018 benefit year risk adjustment methodology in the final rules published in the March 23, 2012 (77 FR 17219) and in the December 22, 2016 editions of the **Federal Register** (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. This final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

⁵ “Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients.” July 27, 2018. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf>.

⁶ “Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year.” July 27, 2018. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf>.

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. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 **Federal Register** (62 FR 16894). 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 guaranteed renewability. In the April 18, 2017 Market Stabilization final rule (82 FR 18346), we released further guidance related to guaranteed availability.

4. 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 March 27, 2012 **Federal Register** (77 FR 18309), we established the original regulatory Navigator duties and training requirements. 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 the 2017 Payment Notice final rule, published in the March 8, 2016 **Federal Register** (81 FR 12204), we expanded Navigator duties and training requirements. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we removed the requirements that each Exchange must have at least two Navigator entities; that one of these entities must be a community and consumer-focused nonprofit group; and that each Navigator entity must maintain a physical presence in the Exchange service area.

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, published 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. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods.

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin⁷ that outlined our intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs 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 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

6. 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 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.

B. Stakeholder Consultation and Input

HHS consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP, and the risk adjustment and risk adjustment data validation programs. We held a number of listening sessions with consumers, providers, employers, health plans, and the actuarial community to gather public input. We solicited input from state representatives on numerous topics, particularly essential health benefits, QHP certification, Exchange establishment, and risk adjustment. 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.

C. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 146, 147, 148, 153, 155, and 156.

The changes to 45 CFR parts 146, 147, and 148 make a non-substantive technical correction to the guaranteed renewability regulations.

The changes to the HHS risk adjustment program established under 45 CFR part 153 relate to the determination of the final coefficients for the 2020 benefit year, and the data sources used to calculate those coefficients. This final rule addresses high-cost risk pooling, where we finalize the same parameters that applied to the 2018 and 2019 benefit years to the 2020 benefit year and future benefit years unless changed in future rulemaking. The finalized provisions in part 153 also relate to the risk adjustment user fee for the 2020 benefit year and modifications to risk adjustment data validation requirements.

The final regulations in 45 CFR part 155 will provide more flexibility related to the training requirements for Navigators by streamlining 20 existing specific training topics into 4 broad categories. They also provide more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible for FFE Navigators, but not required.⁸ They amend and streamline our regulations related to direct enrollment. They also establish a new special enrollment period, at the option of the Exchange, for off-Exchange enrollees who experience a decrease in income and are newly determined to be eligible for APTC by the Exchange. They also increase flexibility for individuals

⁸ This assistance includes: Understanding the process of filing Exchange eligibility appeals; understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange; understanding the availability of exemptions from the requirement to maintain MEC and from the individual shared responsibility payment that are claimed through the tax filing process and how to claim them; the Exchange-related components of the premium tax credit reconciliation process; understanding basic concepts and rights related to health coverage and how to use it; and referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

seeking the general hardship exemption by allowing them to claim the exemption on their federal income tax return for 2018 without obtaining an exemption certificate number from the Exchange. Finally, they include several amendments to the definitions applicable to part 155.

The final regulations in 45 CFR part 156 set forth provisions related to cost sharing, including the premium adjustment percentage, the maximum annual limitation on cost sharing, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2020. As we do every year in the HHS notice of benefit and payment parameters, we are finalizing updates to the premium adjustment percentage, which helps determine the required contribution percentage, the maximum annual limitation on cost sharing, and the reduced maximum annual limitation on cost sharing based on the premium adjustment percentage.

We finalize the FFE and SBE-FP user fee rates for 2020 to be 3.0 and 2.5 percent of premiums, respectively. The final regulations in part 156 also include a policy to incentivize the use of generic drugs. In addition, the final rule at part 156 includes changes related to direct enrollment to conform to the changes finalized to 45 CFR part 155.

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

In the January 24, 2019 **Federal Register** (84 FR 227), we published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020” proposed rule (proposed 2020 Payment Notice or proposed rule). We received 26,129 comments, including 25,632 comments that were substantially similar to one of eight different letters. Comments were received from state entities, such as departments of insurance and state Exchanges; health insurance issuers; providers 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 certain proposed provisions, a summary of the public comments received that directly related to those proposals, our responses to

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

them, and a description of the provisions we are finalizing.

Comment: We received multiple comments criticizing the short comment period, stating that the length of 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 2020 plan 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 continue to try to expand the comment period while also providing industry stakeholders with more time to implement the final rule.

Comment: We received multiple comments criticizing the timing of the release of the proposed rule, stating that publishing the proposal for this annual rule in January 2019 creates challenges for states, Exchanges, issuers, and other entities in implementing changes for plan year 2020.

Response: We recognize the importance of a timely release of updates to our regulations, and make every effort to do so efficiently. After the comment period closed, we took steps to expedite the publication of this final rule. We will continue to support consumers and stakeholders to implement the changes in this final rule in a timely fashion.

Comment: We received numerous comments cautioning us about making changes that would weaken the PPACA.

Response: Our top priority at HHS is putting patients 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 made great strides in working to streamline our regulations and our operations with the goal of reducing unnecessary burden, increasing efficiencies and improving the patient experience. We will continue to seek innovative ways to reduce costs and burden while meeting the health needs of all Americans, within the constraints of the law. We are continuing to address feedback we receive from stakeholders and the public, and in turn we are making changes that will better serve patients

and allow states to address the unique health needs of their populations.

We sought comment on ways to further implement section 1311(e)(3) of the PPACA, as implemented by § 156.220(d), to enhance enrollee cost-sharing transparency. We also sought comment on whether there are any existing regulatory barriers that stand in the way of privately led efforts at price transparency, and ways that we can facilitate or support increased private innovation in price transparency.

We requested comment on automatic re-enrollment processes and capabilities, as well as additional policies or program measures that would reduce eligibility errors and potential government misspending for potential action in future rulemaking.

Comment: Commenters who addressed this topic unanimously supported retaining automatic re-enrollment processes. Supporters cited benefits such as the stabilization of the risk pool due to the retention of lower-risk enrollees who are least likely to actively re-enroll, the increased efficiencies and reduced administrative costs for issuers, the reduction of the numbers of uninsured, and lower premiums. Commenters stated that existing processes, such as eligibility redeterminations, electronic and document-based verification of eligibility information, periodic data matching, and premium tax credit reconciliations, are sufficient safeguards against potential eligibility errors and increased federal spending.

Response: We appreciate commenters' feedback and will take it into consideration as we continue to explore options to improve Exchange program integrity going forward. As we discussed in the preamble to the proposed rule, we agree that automatic re-enrollment significantly reduces issuer administrative expenses, makes enrolling in health insurance more convenient for consumers, and is consistent with broader industry practices. We are not making changes for these processes in this rule but will continue to consider the feedback provided for potential action in future rulemaking applicable not sooner than plan year 2021.

Comment: All commenters that commented on efforts to increase price transparency supported the idea of increased price transparency. Many commenters provided suggestions for how to disclose health care costs to consumers, such as providing costs for common, shoppable services, including costs for both in- and out-of-network health care, and accounting for consumer-specific benefit information

such as progress towards meeting a deductible, out-of-pocket limit and visit limits in health care cost estimates. One commenter supported implementing price transparency requirements across all private markets. Another commenter suggested that price transparency efforts be a part of a larger payment reform, provider empowerment, and patient engagement strategy. Some commenters expressed caution for how such policies should be implemented, warning against duplicating state efforts and passing along administrative costs to consumers, and cautioning that the proprietary and competitive nature of payment data should be protected.

Response: We are not making changes to further implement the enrollee cost-sharing transparency requirements under § 156.220(d) as part of this rule. We will take this input into account as we continue our efforts to promote price transparency in health care markets.

We sought comment on ways that we can promote the offering and take-up of HDHPs that can be paired with HSAs. We also sought comments for ways to increase the visibility of HSA-eligible HDHPs on *HealthCare.gov*.

Comment: Many commenters provided suggestions on how to improve the educational content about HSAs on *HealthCare.gov*, and methods to improve the technical aspects of *HealthCare.gov* to incorporate HSAs into the QHP shopping experience. Commenters also encouraged HHS' involvement in the incorporation of value-based insurance design principles into HSA-eligible HDHP designs.

Response: We appreciate these comments, and will take them under consideration should we make any future changes to our approach towards HSAs on *HealthCare.gov*. We note that the rules for HSAs and HSA-eligible HDHPs are set forth in section 223 of the Code and are under the jurisdiction of the Department of the Treasury and the Internal Revenue Service (IRS).

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

For a discussion of the provisions in this final rule related to part 146, please see the preamble to part 147.

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

Section 147.106 implements the guaranteed renewability requirements under the PPACA (applicable to non-grandfathered plans), and §§ 146.152 and 148.122 implement the guaranteed renewability requirements enacted by HIPAA (applicable to both grandfathered and non-grandfathered

plans). We proposed amendments in § 147.106, and conforming amendments to §§ 146.152 and 148.122, which, taken together with proposed amendments to §§ 156.122 and 156.130, aimed to reduce prescription drug expenditures.

In the 2016 Payment Notice, we expressed concerns about the impact on consumers of mid-year formulary changes. We noted that, under guaranteed renewability requirements and the definitions of “product” and “plan,” issuers generally may not make plan design changes, other than at the time of plan renewal. However, we also stated that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate.⁹

In the proposed rule, we proposed to add § 147.106(e)(5) to set parameters in the individual, small group, and large group markets, for plan years beginning on or after January 1, 2020, for certain mid-year formulary changes, if permitted by applicable state law. At § 147.106(e)(5), we proposed allowing issuers, for plan years beginning on or after January 1, 2020, to make formulary changes during the plan year when a generic equivalent of a prescription drug becomes available on the market, within a reasonable time after that drug becomes available. We proposed that the issuer be permitted to modify its plans’ formularies to add the generic equivalent drug. At that time, the issuer would also be permitted to remove the equivalent brand drug from the formulary or move the equivalent brand drug to a different cost-sharing tier on the formulary. We proposed that any mid-year formulary changes would have to be consistent with the standards applicable to uniform modifications in paragraph (e)(2) or (e)(3).

We proposed that issuers, including issuers of grandfathered plans, would also be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process under § 147.136 or the drug exception request process under § 156.122(c).

Under our proposal, before removing a brand drug from the formulary or moving it to a different cost-sharing tier, a health insurance issuer would be required to notify all plan enrollees of the change in writing a minimum of 60 days prior to initiating the change. This notice would identify the name of the brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier,

provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 or the exceptions processes outlined in § 156.122(c), enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan.

We also proposed changes to § 147.106(a) to reflect that paragraph (e) currently provides an exception to the general rule on guaranteed renewability. This is merely a technical correction, not a substantive change. We similarly proposed technical corrections to §§ 146.152(a) and 148.122(b).

We sought comment on these proposals related to prescription drug benefits and coverage, including whether to limit the proposal related to mid-year formulary changes to the individual and small group markets, and whether a different advance notice period, such as 90 days or 120 days, would be more appropriate.

Comment: While some commenters generally supported the proposal, many commenters opposed it, because they noted it inappropriately expanded or narrowed issuers’ ability to make drug formulary changes mid-year. Several commenters opposed the proposal as overly restrictive. These commenters stated that federal law does not prohibit mid-year formulary changes, and that it is a current practice that occurs much more broadly than what the proposal would permit. For example, these commenters stated that formularies are changed when a biosimilar drug, a lower-priced brand name therapeutic equivalent, a new drug that is clinically effective, or an over-the-counter version of a drug becomes available; when there is a shortage of a preferred generic drug; when there is new evidence of the efficacy of a drug; or when there are expanded indications for a drug. One commenter stated that most states do not prohibit mid-year formulary changes, regardless of the federal guaranteed renewability requirements and stated that mid-year formulary changes should be allowed for all drugs as long as the changes are approved by the issuer’s pharmacy and therapeutics committee, and notice is provided. Several commenters stated that approval by a pharmacy and therapeutics committee, notice to enrollees, and providing an exceptions process to request and gain access to removed drugs when medically appropriate and necessary, are all current industry practice.

Many other commenters stated the proposal would improperly allow mid-year formulary changes and opposed the proposal because they noted it would hurt consumers. These commenters stated, for example, that consumers choose their plans based on the formulary composition at the beginning of the plan year and that changing formularies could result in patient safety and health issues such as additional emergency room visits, additional outpatient appointments, and higher medical costs. A few commenters stated that these dangers could occur notwithstanding the availability of an exceptions or appeals process. Many commenters stated that mid-year formulary changes arbitrarily eliminate an EHB.

Response: In the 2016 Payment Notice, we stated that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate. Comments to this rule supported that belief. At the same time, in the 2016 Payment Notice, we also expressed concerns about the impact on consumers of mid-year formulary changes.¹⁰ We appreciate the comments to this rule identifying potential negative impacts on consumers. Given the complexity of this issue, and the challenges of balancing the interests of consumers with the importance of mitigating the effects of rising prescription drug costs, we are not finalizing the proposal at this time. Rather, we will continue to examine the issue of mid-year formulary changes, and may provide guidance on this issue in the future. In the meantime, to the extent issuers make mid-year formulary changes consistent with applicable state law, our expectation is that all issuers (in the individual, small group and large group markets) will continue to provide certain consumer protections that, as commenters have stated, are generally consistent with current industry practice. These protections include pre-approval by a pharmacy and therapeutics committee, and reasonable advance notice to affected individuals of the mid-year removal of any drug from a formulary (or the placement of any drug on a higher cost-sharing tier). Additionally, we expect that affected individuals will generally have access to the appeals processes outlined in § 147.136 or the exceptions processes outlined in § 156.122(c), under which enrollees and dependents may request and gain access to a non-formulary drug when clinically appropriate and not otherwise covered by the health plan.

⁹ 80 FR at 10822.

¹⁰ 80 FR 10822.

Several commenters specifically noted that issuers currently offer an exceptions process when making mid-year formulary changes. Therefore, our expectation is that issuers will also offer an appeals process or exceptions process when making mid-year formulary changes.

We do not agree that mid-year formulary changes arbitrarily eliminate an EHB. Rather, we remind issuers that all requirements in § 156.122 related to EHB as applied to prescription drug coverage continue to apply in the context of mid-year formulary changes. For example, a health plan does not provide EHB unless it covers the greater of one drug in every United States Pharmacopeia (USP) category and class or the same number of prescription drugs in each category and class as the EHB-benchmark plan. Additionally, the EHB regulations at § 156.122(a)(3) require the use of a pharmacy and therapeutics committee to establish and manage the formulary drug list throughout the year. Issuers required to provide EHB must continue to meet these requirements.

Comment: Many commenters, including those who generally support and those who generally oppose the proposal, requested specific changes to the proposal. One commenter favored applying mid-year formulary restrictions to issuers in the large group market, while a few opposed doing so. One commenter stated that the uniform-modification-of-coverage requirements should not apply to mid-year formulary changes in the large group market, while another stated they should not apply in any market. One commenter raised what it believed to be practical concerns with any restrictions on mid-year formulary changes in the group markets, since plan years in those markets are not required to align with the calendar year. Many commenters stated that mid-year formulary changes should be permitted as a way to add drugs, but not to remove drugs or move drugs to a different tier. A few commenters stated the formulary changes should not apply, for the rest of the plan year, to people already taking the affected drugs. Several commenters noted that we did not define “generic drug,” and offered definitions.

Response: As stated in this rule, we are not finalizing the proposal at this time, and instead intend to continue to examine the issue of mid-year formulary changes. We appreciate the important considerations raised by commenters, in particular regarding the practical concerns with restrictions on mid-year formulary changes, and believe it is important for us to more fully explore these issues and other issues raised by

commenters prior to issuing further guidance. We will consider all of these comments as we consider future guidance in this area.

We also are not finalizing any changes to the definitions of “plan” and “product” at § 144.103—which incorporate by reference the uniform modification standards—with regard to determining whether a product and plan that have undergone formulary changes are considered the same product and plan. This definition provides that, among other things, within a product, each plan must have the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal level of coverage. We interpret this provision to mean that for modifications of prescription drug formularies, each tier must continue to have the same cost-sharing structure, or any changes to the tier structure must be related to changes in cost or utilization of medical care, or to maintain the same metal level, to be considered a uniform modification of coverage, regardless of any changes made to the placement of drugs within the formulary. Additionally, the product must provide the same covered benefits, except for any changes in benefits that cumulatively impact the plan-adjusted index rate for any plan within the product within an allowable variation of ± 2 percentage points (not including changes pursuant to applicable federal or state requirements). Given the nature of formulary changes, our expectation is that generally, any changes to which drugs are covered under the formulary would not be of a magnitude that would exceed the allowable variation of ± 2 percentage points of the plan-adjusted index rate. However, if formulary changes do result in a change to the plan-adjusted index rate outside this permitted variation, such changes would result in the product being considered to have been discontinued, and a new product to have been issued.

Comment: While many commenters generally supported the requirement for issuers to provide an appeals or exceptions process, a few commenters recommended requiring an exceptions process of all issuers, suggesting it is more protective than the appeals process. We did not receive any comments that generally opposed such a requirement. In describing current industry practice, multiple commenters pointed out that issuers making mid-year formulary changes already regularly provide affected consumers with access to the exceptions process.

Response: We agree with commenters that access to an appeals or exceptions process when a mid-year formulary change occurs is an important consumer protection. Although we are not finalizing our proposal, we note that issuers offering non-grandfathered group or individual health insurance coverage are required to provide an appeals or exceptions process under which enrollees and dependents may request and gain access to a non-covered drug, including one that was removed from the formulary (other than one removed for safety reasons) when clinically appropriate and not otherwise covered by the health plan, under §§ 147.136 or 156.122(c), as applicable. We expect issuers to continue to do so, with respect to mid-year formulary changes.

Comment: For the proposed notice requirement, many commenters generally agreed that a notice requirement is necessary, while only one stated otherwise. Many commenters agreed with the proposed 60-day advance notice requirement, while many advocated for a 90-day or 120-day requirement. A few commenters stated it should be 30 days, consistent with the notice Medicare requires under some circumstances. Many commenters stated that the notice should be sent only to affected enrollees, while others stated the notice should also be sent to prescribers and pharmacies. A few commenters requested either a template or specific language. A few commenters stated that a two-step notice should be provided: The first notice should apprise enrollees of the availability of the generic drug, as well as any cost advantage to switching; at least 90 days later, the issuer must provide a second notice, stating that changes to the brand drug’s cost sharing will occur; and only 60 days after the second notice is sent, could the issuer change the brand drug’s cost sharing. A few commenters stated that state law should determine the timing and content of notices. Several commenters stated that notice to enrollees is common industry practice when mid-year formulary changes occur.

Response: We agree with the many commenters who stated that providing advance notice to affected consumers is important, and although we are not finalizing the proposal at this time, we expect issuers will continue to provide reasonable notice to affected consumers, pending any further guidance on mid-year formulary changes. We will continue to examine this issue.

We received no comments on the proposed technical corrections to

§§ 146.152, 147.106, and 148.122, and are finalizing them as proposed.

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

For a discussion of the provisions in this final rule related to part 148, please see the preamble to part 147.

D. 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 2019,¹¹ both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2019 sequestration. The federal government's 2019 fiscal year began October 1, 2018. Although the 2016 benefit year was the final year of the transitional reinsurance program, we continue to make reinsurance payments in the 2019 fiscal year for close-out activities. Therefore, the risk adjustment and reinsurance programs will be sequestered at a rate of 6.2 percent for payments made from fiscal year 2019 resources (that is, funds collected during the 2019 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 (Pub. L. 99–177, enacted on December 12, 1985), as amended, and the underlying authority for the reinsurance and risk adjustment programs, the funds that are sequestered in fiscal year 2019 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2020 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs will be sequestered in future fiscal years, and any sequestered funding will become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters for the Risk Adjustment Program

In subparts A, B, D, G, and H 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-than-average risk, risk

adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual and small group markets (including merged 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. HHS did not receive any requests from states to operate risk adjustment for the 2020 benefit year. Therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2020 benefit year.

a. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The current structure of these models is described in the 2019 Payment Notice.¹² The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each age group. In 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, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXC) beginning with the 2018 benefit year. 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 reduction adjustment that accounts for differences in induced demand at various levels of cost sharing.

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 or PLRS) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the state payment or charge that an issuer will receive or be required to pay for that plan. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

i. Definitions (§ 153.20)

In this final rule, we are making a technical correction to the definition of a risk adjustment covered plan under § 153.20 by correcting a citation in the definition of "risk adjustment covered plan" from § 146.145(c) to § 146.145(b). Specifically, this definition was finalized in the final rule entitled Standards Related to Reinsurance, Risk Corridors and Risk Adjustment,¹³ and after that rule was finalized, the final rule entitled Amendments to the HHS Notice of Benefit and Payment Parameters for 2014¹⁴ amended and redesignated the numbering under § 146.145. Among other things, these amendments moved the excepted benefit provision from paragraph (c) to paragraph (b) of § 146.145. Thus, the purpose of this technical correction is to update this citation to refer to the paragraph on excepted benefit plans under § 146.145, consistent with the original intent of this definition when it was first adopted.

ii. Updates to the Risk Adjustment Model Recalibration

We used the 3 most recent years of MarketScan® data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. For the 2019 benefit year, we recalibrated the models using 2 years of MarketScan® data (2014 and 2015) and 2016 enrollee-level EDGE data. The 2019 benefit year was the first recalibration year in which enrollee-level EDGE data was used for this purpose. This approach used blended (averaged) coefficients from 3 years of separately solved models to provide stability for the risk adjustment coefficients year-to-year, while reflecting the most recent years' claims experience available. For the 2020 benefit year, we proposed to blend the 2 most recent years of enrollee-level EDGE data available (2016 and 2017) with the most recent year of MarketScan® data available (2017). We also noted that if we are unable to publish the final coefficients in the final rule, consistent with § 153.320(b)(1)(i), and as we have done for certain prior benefit years,¹⁵ we would publish the final coefficients for the 2020 benefit year in guidance after the publication of the final rule. We sought comments on these proposals.

¹³ 77 FR 17220 (March 23, 2012).

¹⁴ 78 FR 65046 (October 30, 2013).

¹⁵ For example, see 2018 Payment Notice final rule, 81 FR 94058 (December 22, 2016). Also see <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Final-HHS-RA-Model-Coefficients.pdf>.

¹¹ "OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2019", p. 6. February 12, 2018. Available at https://www.whitehouse.gov/wp-content/uploads/2018/02/Sequestration_Report_February_2018.pdf.

¹² See 83 FR 16930 at 16939.

We did not propose to make any changes to the categories included in the HHS risk adjustment models for the 2020 benefit year from those finalized in the 2019 benefit year models. That is, we proposed to maintain the same age, sex, enrollment duration, HCC, RXC, and severity categories for the 2020 benefit year models as those used for the 2019 benefit year models.¹⁶ However, we proposed to make a pricing adjustment for one RXC coefficient for the 2020 benefit year adult models. Consistent with our treatment of other RXCs where we constrain the RXC coefficient to the average cost of the drugs in the category,¹⁷ we proposed to make a pricing adjustment to the Hepatitis C RXC to mitigate overprescribing incentives in the 2020 benefit year adult models. For the RXC coefficients listed in Table 1 of the proposed rule, we constrained the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs. This had the material effect of reducing the Hepatitis C RXC and the RXC–HCC interaction coefficients. For the final 2020 benefit year Hepatitis C factors in the adult models, we proposed to adjust the plan liability associated with Hepatitis C drugs to reflect future market pricing of Hepatitis C drugs before solving for the adult models' coefficients. We proposed applying an adjustment to the plan liability to ensure that plans can continue to receive incremental credit for enrollees having both the RXC and HCC for Hepatitis C, and allow for differential plan liability across metal levels. We sought comment on these proposals.

We are not finalizing our proposal to blend the most recent year of MarketScan® data (2017) with the 2 most recent years of enrollee-level EDGE data (2016 and 2017) for 2020 risk adjustment model recalibration. We are instead finalizing an approach that would blend 3 consecutive years of data—one year of data from MarketScan® (2015) with the 2 most recent years of enrollee-level EDGE data (2016 and 2017), an approach that more closely aligns with the approach we used to recalibrate risk adjustment models for the 2016, 2017, 2018, and 2019 benefit years. This approach maintains our previously finalized

policy of blending coefficients from 3 years of separately solved models and promotes stability for the risk adjustment coefficients year-to-year. Accordingly, we have incorporated the 2015 MarketScan® data with 2016 and 2017 benefit year enrollee-level EDGE data for the final 2020 benefit year risk adjustment coefficients presented in this final rule. Additionally, we are finalizing the pricing adjustment to the plan liability simulation for the Hepatitis C RXC, as proposed, and are not otherwise making changes to the categories included in the HHS risk adjustment models for the 2020 benefit year from those finalized for the 2019 benefit year models.

The following is a summary of the public comments we received on the risk adjustment model recalibration proposals.

Comment: Most commenters supported using enrollee-level EDGE data to recalibrate the risk adjustment models, with some commenters especially supporting the blending of 2016 and 2017 enrollee-level EDGE data and 2017 MarketScan® data for the recalibration of the 2020 risk adjustment models. Some commenters stated that they had expected the 2020 benefit year models to incorporate coefficients solved from the 2015 MarketScan® data to maintain 2 of the same data years (2015 MarketScan and 2016 enrollee-level EDGE) as those used in the 2019 benefit year models. These commenters raised concerns that using 2017 MarketScan® and 2017 enrollee-level EDGE data may result in double counting certain enrollees to the extent the individual and small group market plans contribute data to MarketScan®, and suggested that using currently available 2015 MarketScan® data with 2016–2017 enrollee-level EDGE data to recalibrate the 2020 risk adjustment models would allow the final coefficients to be published with the final rule. One of these commenters was concerned about volatility in coefficients relative to prior years, which blended 3 consecutive years of data (rather than 2 data sets from the same year), wanting more information on whether this volatility would be reduced if 2015 MarketScan® data were used. Some commenters supported HHS' intent to propose use of 3 consecutive years of enrollee-level EDGE data to recalibrate the risk adjustments models for the 2021 benefit year and beyond. One commenter supported maintaining the categories included in the HHS risk adjustment models for the 2020 benefit year.

Response: We believe blending multiple years of data promotes stability

and certainty for issuers in rate setting, helping to smooth significant differences in coefficients solved from any one year's dataset, particularly for conditions with small sample sizes. Because the MarketScan® data generally represent enrollees in the large self-insured employer market and the enrollee-level EDGE data represents enrollees in the small group and individual markets, using two datasets from the same year (2017 MarketScan® and 2017 enrollee-level EDGE) would not significantly double count enrollees between the different datasets for the 2017 benefit year. However, we agree with commenters who noted that maintaining 2 years of data from one recalibration year to the next has a stabilizing effect by spreading the impact of new experience over 3 years. We recognize and agree with the concerns that recalibrating the 2020 benefit year risk adjustment models blending 2017 MarketScan® data with 2016 and 2017 enrollee-level EDGE data may create unintentional volatility, as it would only maintain one of the three datasets that were used in the 2019 benefit year recalibration. Based on comments received, we are finalizing the 2020 benefit year risk adjustment models using blended coefficients from 2015 MarketScan® data, and 2016 and 2017 enrollee-level EDGE data. We intend to continue our efforts to recalibrate the risk adjustment models using enrollee-level EDGE data from issuers' individual and small group or merged market populations, and transition away from the MarketScan® commercial database. Specifically, beginning with the 2021 benefit year, we intend to propose to use the 3 most recent years of enrollee-level EDGE data available to recalibrate the risk adjustment models.

Comment: Several commenters requested that HHS provide the final coefficients in the final rule and the actual proposed coefficients to be proposed in proposed rules in future years. However, one commenter requested that the final coefficients be made available by March 31, 2019 due to state filing deadlines.

Response: We appreciate the commenter's concern that the final coefficients be made available by the time of initial state rate filing submissions. Our ability to provide the proposed and final coefficients in the proposed and final rules depends on the availability of data and our ability to execute the model regressions with that data to solve the coefficients for the risk adjustment models for a given benefit year, reflecting any applicable

¹⁶ See 83 FR 16939.

¹⁷ See Section 4.0, "Constraints on RXC Coefficients to Limit Incentives for Inappropriate Prescribing" of the Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCUIs) to HHS Drug Classes (RXC) Crosswalk Memo. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf>.

modifications adopted as part of the rulemaking process.

Due to the availability of data and our ability to execute the model regressions, this year, we are able to provide the final recalibrated coefficients for 2020 benefit year in the tables below. In the future, we will continue to look for opportunities to update our processes to obtain and process the recalibrated coefficients as soon as practical. However, if data is not available or if we are unable to calculate the coefficients for the risk adjustment models for a benefit year in time for publication in the applicable final annual HHS notice of benefit and payment parameters, then we will publish the draft factors to be employed in the models in the final rule, including demographic factors, diagnostic factors, and utilization factors, and the datasets to be used to calculate the final coefficients.¹⁸ In such circumstances, we will also notify issuers in the final rule of the date by which final coefficients will be released in guidance.¹⁹

Comment: One commenter encouraged HHS to monitor the volatility of coefficients year-to-year in switching to enrollee-level EDGE data. One commenter recommended evaluating the models continually to ensure they fully capture the cost of the current standard of care for conditions. One commenter recommended HHS continue to contemplate the best way to incorporate drug pipeline data, while a different commenter supported continuing to reevaluate drugs. Another commenter supported monitoring and evaluating the impact on patient access of changes to the risk adjustment program.

Response: As with every recalibration year, we continue to monitor the year-to-year changes in risk scores, including the volatility of the coefficients from year to year. As discussed in the proposed rule, we noted that for HCCs with corresponding RXCs and RXC–HCC interaction factors in the adult risk adjustment models, we are observing year-to-year fluctuations in the risk score weights between the HCC, RXC, and RXC–HCC interaction factors. This fluctuation is mainly due to the collinearity between these factors, making the statistical models, and therefore, the coefficients solved for these factors, sensitive to small changes in the data. Although the HCC, RXC, and RXC–HCC interaction factors may be changing from year to year, the aggregate impact of the factors has remained relatively stable between

recalibration updates. Similarly, the aggregate impact of the HCC, RXC and RXC–HCC interaction factors for the 2020 benefit year continues to be relatively stable.

Additionally, we have been continuously assessing the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment model. As a result of this on-going assessment, we make quarterly updates to the RXC Crosswalk²⁰ to ensure drugs, including new drugs, are being mapped to RXCs where appropriate, and intend to continue to make these updates in the future.

Overall, we also continue to regularly evaluate the individual and small group markets (including merged markets) and assess whether updates to the HHS-operated risk adjustment program could improve the assessment of plan actuarial risk. We also regularly review the impact of the risk adjustment program on the markets. We expect to continue to review the risk adjustment program and propose changes as necessary.

Comment: Most commenters generally supported a pricing adjustment for the Hepatitis C RXC coefficient to reflect changing drug prices. A few commenters were concerned that the proposal is over-adjusting the Hepatitis C RXC coefficient, and wanted clarification on the approach used for the adjustment. One commenter stated that HHS should modify the Hepatitis C RXC adjustment based on a days' supply variable. While some commenters agreed with the adjustment to Hepatitis C RXC to mitigate against the potential for misaligned incentives such as overprescribing, others disagreed with the implication that health plans influence providers' prescribing patterns.

Response: We found significant pricing changes due to the introduction of new Hepatitis C drugs into the market upon review of the Hepatitis C treatments that are approved and expected to be available before the 2020 benefit year.²¹ Due to the lag between

the data years used to recalibrate the risk adjustment models and the applicable benefit year, the data used for recalibrating the models do not precisely reflect the average cost of Hepatitis C treatments applicable to the benefit year in question. In addition, the first few years of enrollee-level EDGE data do not include days' supply information for the RXCs; thus, the enrollee-level EDGE datasets could not be used to model a variable for the days' supply of the Hepatitis C RXC. Since we are finalizing the risk adjustment models for the 2020 benefit year coefficients with the 2015 MarketScan[®] data, which represents even older and costlier Hepatitis C trends than what is anticipated in the 2020 benefit year, we continue to believe the pricing adjustment as proposed is appropriate.

We believe the pricing adjustment, as finalized, is appropriate based on our review of published expectations for plan liability associated with Hepatitis C drugs. Additionally, we agree with commenters that due to the high cost of these drugs, without a pricing adjustment to plan liability, issuers would be overcompensated for the Hepatitis C RXC in the 2020 benefit year and could be incentivized to “game” risk adjustment or encourage overprescribing practices. We appreciate the commenters' view that plans generally do not influence prescribing patterns. However, to avoid perverse incentives to influence overprescribing behavior, we are finalizing the pricing adjustment as proposed. This pricing adjustment leads to Hepatitis C RXC coefficients that better reflect anticipated actual 2020 benefit year plan liability associated with Hepatitis C drugs.

As such, we are finalizing our proposed pricing adjustment to make a pricing adjustment to more closely reflect the expected average additional plan liability of the Hepatitis C RXC for the 2020 benefit year. In making this determination, we consulted our clinical experts to assess whether the lower cost Hepatitis C drugs are substitutable to ensure that plans that cover various treatments would continue to be compensated for their incremental plan liability. We found that due to the generic entrant, prices for all variations of Hepatitis C drugs are expected to be significantly lower in the 2020 benefit year than those observed in the currently available datasets (which reflect prior benefit years). We believe this approach to estimating the Hepatitis

gilead-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.

²⁰ April 4, 2019, was our last update of the 2018 Benefit Year Risk Adjustment (RA): Updated HHS-Developed Risk Adjustment Model Algorithm “Do It Yourself (DIY)” Software—Technical Details that includes the RXC Crosswalk. The RXC Crosswalk is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-DIY-Tables-2018.xlsx>.

²¹ See <https://www.gilead.com/news-and-press/press-room/press-releases/2018/9/gilead-subsidiary-to-launch-authorized-generics-of-epclusa-sofosbuvirvelpatasvir-and-harvoni-ledipasvirsofosbuvir-for-the-treatment-of-chronic-hepatitis-c>. Also see <https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevir>

¹⁸ See § 153.320(b)(1)(i).

¹⁹ *Ibid.*

C plan liability appropriately balances reflecting the changes in costs of the Hepatitis C drugs in the market in the 2020 benefit year while limiting the potential for overprescribing incentives. We intend to reassess this pricing adjustment in future benefit years' model recalibrations with additional year of enrollee-level EDGE data.

Comment: Several commenters wanted HHS to consider incorporating the Pre-Exposure Prophylactics (PrEP) into the risk adjustment models, given the recent draft United States Preventive Services Task Force (USPSTF) Grade A recommendation²² for clinicians to offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition, citing that the high cost for PrEP therapy is likely to lead to cost avoidance strategies by issuers. One commenter expressed support for including preventive services in the risk adjustment models.

Response: We appreciate the commenters noting the draft USPSTF recommendation, which, if finalized, would require issuers to cover a high cost-therapy with no cost sharing. However, we are not incorporating PrEP into the risk adjustment models. As a general principle, RXCs are incorporated into the HHS risk adjustment models to impute a missing diagnosis or indicate severity of a diagnosis. While preventive services are incorporated in the simulation of plan liability, they do not directly affect specific diagnoses. We incorporate preventive services into our models to ensure that 100 percent of those services are reflected in the plan's liability; however, many preventive services only count as preventive services under certain conditions. In the case of PrEP and the draft USPSTF recommendation, the recommendation is only applied if the enrollee meets certain conditions for "persons who are at high risk." Some of the at-risk categories are not recorded in claims data, making them impossible to identify. Furthermore, the USPSTF recommendation for PrEP is only a draft recommendation, and we do not know if or when it would become final. We also note that we are aware of other current drugs that are preventive in nature that may be similar to PrEP in that they are medications recommended for a subset population that is at risk. While we do not plan to make an

adjustment for PrEP at this time, we may consider soliciting comments in the future on whether and how to incorporate preventive medications into the risk adjustment models, and how to identify at-risk populations in the enrollee-level EDGE data that may be eligible for drugs classified as preventive services.

Comment: Some commenters noted concern about the enrollment duration factors in the adult models, and wanted HHS to consider further adjustments to these factors. For example, certain commenters discussed the differences between special enrollment period enrollees versus open enrollment period enrollees that drop coverage during the plan year. These commenters noted concerns that the current combined enrollee duration factors do not adequately address both scenarios, and wanted the enrollment duration factors to vary for these different scenarios. In particular, one of these commenters expressed concerns about the changes in the enrollment duration factors over time, stating that the factors never seemed to correctly adjust for increased special enrollment period spending (particularly for those with the maternity HCC), and provided several recommendations on potential modifications to improve the enrollment duration factors, including special consideration for maternity and NICU-related HCCs. Another commenter requested that HHS take a holistic look at the child risk scores and whether duration factors would be appropriate for incorporation into the child models, as well as the relationship of duration factors with risk scores to age rating factors. One commenter supported HHS making adjustments to give greater weight to the enrollee-level EDGE data when recalibrating the model coefficients if HHS finds significant demographic or distributional differences in the enrollee-level EDGE data compared to the MarketScan® data, and was supportive of HHS continuing to analyze the enrollee-level EDGE data to study key differences between the individual and small group markets, including costs, utilization patterns, induced demand, and partial year enrollment.

Response: While there are differences in total spending in MarketScan® data compared to enrollee-level EDGE data, we have found that the relative risk differences for age-sex, HCC, and RxC categories in the enrollee-level EDGE data are generally similar to those in the MarketScan® data. Therefore, we do not believe giving greater weight to the enrollee-level EDGE data is needed. Since the 2016 Risk Adjustment White

Paper and Conference,²³ we have continued to assess options to update the enrollment duration factors in the risk adjustment adult models as we stated we would. With the 2017 enrollee-level EDGE data, we are now able to analyze whether to modify enrollment duration factors with a lens of differences between individual and small group markets, since the market identifier was not part of the 2016 enrollee-level EDGE data. Our preliminary analysis of 2017 enrollee-level EDGE data found that separate enrollment duration factors for the individual and small group markets in the adult models may be warranted, given the differences in risk profiles of partial year enrollees between the two markets. Small group market partial year enrollees had a lower incremental risk on average than the individual market partial year enrollees in the 2017 benefit year data. Additionally, we did not observe a significant additional risk for special enrollment period enrollees or enrollees who dropped coverage prior to the end of the benefit year in either market.

We did not propose and are not making any change to the current enrollment duration factors used in the adult risk adjustment models at this time. Our goal is to continue to analyze enrollee-level EDGE data; we will consider proposing changes to how partial year enrollees are accounted for in the risk adjustment models for future benefit years in notice-and-comment rulemaking. We intend to solicit feedback and recommendations in the future for potential updates to how partial year enrollees are accounted for in the risk adjustment models, including adjustments to the enrollment duration factors and the use of separate enrollment duration factors for individual and small group markets and may consider whether such factors should be incorporated in the child models.

iii. High-Cost Risk Pooling (§ 153.320) and Accounting for the High-Cost Risk Pool in the Risk Adjustment Transfer Methodology

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 HHS risk adjustment models.²⁴ Specifically, we finalized adjusting the models for high-cost enrollees in risk

²² U.S. Preventive Services Task Force, "Draft Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis" (2018) available at <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

²³ <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf> and https://www.regtag.info/uploads/library/RA_ConferenceSlides_033116_5CR_040516.pdf.

²⁴ 81 FR 94058 at 94080 (December 22, 2016).

adjustment covered plans beginning with the 2018 benefit year by excluding a percentage of costs above a certain threshold in the calculation of enrollee-level plan liability risk scores so that risk adjustment factors are calculated without the high-cost risk, since 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 high-cost enrollees, issuers of risk adjustment covered plans will receive a percentage of costs (coinsurance rate) above the threshold. We set the threshold and coinsurance rate at levels that will continue to incentivize issuers to control costs while improving the predictiveness of the HHS risk adjustment models. Issuers of risk adjustment covered plans with high-cost enrollees will receive a payment for the percentage of costs above the threshold in their respective transfers for the applicable benefit year. Using claims data submitted to the EDGE servers by issuers of risk adjustment covered plans, we calculate the total amount of paid claims costs for high-cost enrollees based on the threshold and the coinsurance rate. We 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 is applied to the total transfer amount in each market, thus maintaining the balance of payments and charges within the HHS-operated risk adjustment program. 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 and 2019 benefit years.²⁵ For the 2020 benefit year and beyond, we proposed to maintain the same parameters that apply to the 2018 and 2019 benefit years, unless amended through notice and comment rulemaking.

Additionally, beginning with the 2018 benefit year, we added to the HHS risk adjustment methodology additional transfer terms to reflect the payments and charges assessed for 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 are calculated separately from the state payment transfer formula in the HHS-operated risk adjustment transfer methodology. Beginning for the 2018

benefit year, we finalized the addition of a term that reflects 60 percent of costs above \$1 million (*HRP*), and another term that reflects a percentage of premium adjustment to fund the high-cost risk pool and maintain the balance of payments and charges within the HHS-operated risk adjustment program for a given benefit year. We described in detail in the 2019 Payment Notice how these terms will be calculated in conjunction with the calculations under the state payment transfer formula for the 2019 benefit year.²⁶ These terms are described in detail in this rule, along with the calculations under the total state payment transfer formula, and are also highlighted as part of the illustration of the total risk adjustment transfer methodology below.

Similar to the 2019 benefit year, consistent with the proposed adoption of the same high-cost risk pool parameters (that is, a \$1 million threshold and 60 percent coinsurance rate), we proposed to add a term that would reflect 60 percent of costs above \$1 million (*HRP*) in the total plan transfer calculation and another term that would reflect a percentage of premium adjustment to fund the high-cost risk pool and maintain the balance of payment and charges within the HHS-operated risk adjustment program for a given benefit year. We proposed to use a percentage of premium adjustment factor that would be applied to each plan's total premium amount, rather than the percentage of PMPM premium adjustment factor, consistent with the approach finalized in the 2019 Payment Notice. The percentage of premium adjustment factor applied to a plan's total premium amount would result in the same adjustment as a percentage of the PMPM premium adjustment factor applied to a plan's PMPM premium amount and multiplied by the plan's number of billable member months. We proposed to apply these same terms for future benefit years that maintain the same underlying parameters for the high-cost risk pool adjustment (that is, \$1 million threshold and 60 percent coinsurance rate).

We are finalizing the high-cost risk pool parameters and the additional terms to account for the high-cost risk pool in the risk adjustment transfer methodology as proposed for the 2020 benefit year and for future benefit years unless changed in notice-and-comment rulemaking. The following is a summary of the public comments we received on our proposal on the high-cost risk pool parameters and how to account for the

high-cost risk pool in the risk adjustment transfer methodology.

Comment: Most commenters supported maintaining the high-cost risk pool parameters at the \$1 million threshold and 60 percent coinsurance rate. One commenter disagreed with the high-cost risk pool methodology due to concerns that issuers may try to "game" the system by inflating the cost of high cost services to push payments over the threshold, and stated that the methodology creates another level of uncertainty that insurers will need to factor into their premiums. This commenter stated that if HHS wants to continue the reinsurance program, it should be pursued outside of risk adjustment, and suggested HHS should instead create a permanent reinsurance program, using Medicare pricing to reprice all claims over \$1 million and account for geographic pricing variations in its calculation of the high-cost risk pool payment and charge terms. One commenter cautioned against drastically changing the parameters from year to year which could result in instability, and supported the national funding approach for this aspect of the HHS risk adjustment program, as it maintains a balance between the level of assessments applied to support the program and the allowance for some risk-pooling across states or geographic areas. One commenter noted the importance for states to consider the high-cost risk pool program when designing state-based reinsurance programs, and that section 1332 waiver applications should address the potential overlap between the section 1332 program and the federal risk adjustment program to minimize the likelihood of federal taxpayers compensating issuers twice for the same high value claims. One commenter recommended HHS solicit feedback on possible changes in a separate rulemaking to incorporate a high-cost risk pool stratification methodology, to consider adoption of multiple high-cost pool thresholds with increased coinsurance amounts, and to adjust the issuer charge calculation methodology to avoid penalizing lower-cost issuers. Another commenter requested the ability to comment on the high-cost risk pool parameters each benefit year. Some commenters requested that data on the specific transfer amounts attributable to the high-cost risk pool adjustment, with charges and claims reimbursed reported separately, be sent to issuers in the EDGE reports, and that HHS publish the net amount (reimbursed claims—charges) by state and issuer in the

²⁵ See 81 FR 94058 at 94080 and 83 FR 16930 at 16943.

²⁶ See 83 FR 16930 at 16954.

annual summary risk adjustment report with one requesting high-cost risk pool information in the interim risk adjustment report.

Response: We are finalizing the high-cost risk pool parameters and the approach for accounting for the high-cost risk pool payment and charge terms in the risk adjustment payment transfer methodology as proposed. As detailed in the 2018 Payment Notice,²⁷ we incorporated a high-cost risk pool calculation into the HHS risk adjustment methodology to mitigate any residual incentive for risk selection to avoid high-cost enrollees, and to ensure that, consistent with the statute, transfers better reflect the average actuarial risk of risk adjustment covered plans. It is not intended to be a continuation of the transitional reinsurance program established under section 1341 of the PPACA that ended at the conclusion of the 2016 benefit year. We continue to believe a \$1 million threshold and 60 percent coinsurance rate for the 2020 benefit year and beyond are appropriate to incentivize issuers to control costs while improving risk prediction under the HHS risk adjustment models. Furthermore, we believe the \$1 million threshold and 60 percent coinsurance rate will result in total high-cost risk pool 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 also believe that maintaining the same threshold and coinsurance rate from year-to-year will help promote stability and predictability for issuers, and for all of these reasons, we are finalizing the \$1 million threshold and 60 percent coinsurance rate for 2020 benefit year and beyond without requiring notice and comment on the high-cost risk pool thresholds each year. We intend to release information about the 2018 benefit year high-cost risk pool payment amounts, and the percent of premium charged by the high-cost risk pool in the 2018 benefit year summary risk adjustment report released under § 153.310(e), and would follow a similar approach for future benefit years. We appreciate the comments suggesting various potential changes to the high-cost risk pool methodology. Once we have results and experience from the initial years of the high-cost risk pool in the HHS risk adjustment program, we intend to analyze those results including considering the geographic variation within those results. If we were to seek to make changes to these parameters for benefit years beyond 2020, we would do so through notice-and-comment rulemaking prior to any changes being implemented.

We encourage states considering a state-based reinsurance program to consider the interplay between the high-cost risk pool adjustment in the HHS-operated risk adjustment program and

any state-based reinsurance program. We have provided technical guidance to states considering state-based reinsurance programs to assist them in designing such programs in a manner that avoids double compensating for costs that would otherwise be compensated under the risk adjustment methodology, including the high-cost risk pool adjustment.

iv. List of Factors To Be Employed in the Risk Adjustment Models (§ 153.320)

The factors resulting from the equally weighted blended factors from the 2015 MarketScan® data and the 2016 and 2017 enrollee-level EDGE data separately solved models, including the finalized constraints for the Hepatitis C RXC coefficient, are shown in Tables 1, 3, and 4. For the purposes of the below coefficients, the adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the \$1 million threshold.

Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, and enrollment duration coefficients. Table 2 contains the HHS HCCs in the severity illness indicator variable. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant model maturity and severity categories, respectively.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21–24, Male	0.149	0.117	0.079	0.043	0.039
	Age 25–29, Male	0.143	0.111	0.072	0.035	0.030
	Age 30–34, Male	0.170	0.131	0.085	0.039	0.033
	Age 35–39, Male	0.208	0.161	0.106	0.051	0.045
	Age 40–44, Male	0.251	0.198	0.136	0.074	0.067
	Age 45–49, Male	0.294	0.234	0.165	0.094	0.086
	Age 50–54, Male	0.381	0.311	0.229	0.144	0.134
	Age 55–59, Male	0.427	0.348	0.259	0.166	0.154
	Age 60–64, Male	0.476	0.386	0.286	0.180	0.167
	Age 21–24, Female	0.233	0.185	0.122	0.061	0.054
	Age 25–29, Female	0.263	0.208	0.139	0.070	0.061
	Age 30–34, Female	0.350	0.282	0.203	0.124	0.115
	Age 35–39, Female	0.422	0.346	0.261	0.177	0.167
	Age 40–44, Female	0.467	0.382	0.288	0.194	0.183
	Age 45–49, Female	0.478	0.389	0.289	0.188	0.175
	Age 50–54, Female	0.523	0.430	0.324	0.211	0.197
	Age 55–59, Female	0.501	0.407	0.299	0.185	0.171
	Age 60–64, Female	0.508	0.409	0.295	0.174	0.158
Diagnosis Factors						
HCC001	HIV/AIDS	2.965	2.679	2.477	2.398	2.390

²⁷ 81 FR 94080.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/ Shock.	7.468	7.261	7.144	7.172	7.180
HCC003	Central Nervous System Infections, Except Viral Meningitis.	5.477	5.397	5.344	5.361	5.363
HCC004	Viral or Unspecified Meningitis	4.437	4.230	4.106	4.022	4.012
HCC006	Opportunistic Infections	5.920	5.844	5.796	5.758	5.753
HCC008	Metastatic Cancer	21.104	20.616	20.288	20.316	20.320
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	10.886	10.539	10.306	10.268	10.263
HCC010	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	5.254	5.018	4.850	4.768	4.757
HCC011	Colorectal, Breast (Age <50), Kidney, and Other Cancers.	3.851	3.620	3.454	3.369	3.358
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.502	2.333	2.208	2.127	2.116
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.108	0.981	0.874	0.754	0.738
HCC018	Pancreas Transplant Status/Complications.	4.008	3.806	3.686	3.681	3.682
HCC019	Diabetes with Acute Complications	0.470	0.406	0.345	0.281	0.273
HCC020	Diabetes with Chronic Complications	0.470	0.406	0.345	0.281	0.273
HCC021	Diabetes without Complication	0.470	0.406	0.345	0.281	0.273
HCC023	Protein-Calorie Malnutrition	11.139	11.127	11.117	11.204	11.215
HCC026	Mucopolysaccharidosis	2.368	2.269	2.192	2.130	2.122
HCC027	Lipidoses and Glycogenosis	2.368	2.269	2.192	2.130	2.122
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders.	2.368	2.269	2.192	2.130	2.122
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders.	2.368	2.269	2.192	2.130	2.122
HCC034	Liver Transplant Status/Complications.	9.422	9.331	9.272	9.246	9.242
HCC035	End-Stage Liver Disease	4.595	4.386	4.253	4.225	4.222
HCC036	Cirrhosis of Liver	1.282	1.152	1.065	0.999	0.991
HCC037_1	Chronic Viral Hepatitis C	0.847	0.741	0.667	0.594	0.586
HCC037_2	Chronic Hepatitis, Other/Unspecified	0.847	0.741	0.667	0.594	0.586
HCC038	Acute Liver Failure/Disease, Including Neonatal Hepatitis.	4.287	4.119	4.015	3.981	3.978
HCC041	Intestine Transplant Status/Complications.	31.374	31.347	31.328	31.345	31.346
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.	9.205	8.962	8.803	8.803	8.804
HCC045	Intestinal Obstruction	5.389	5.146	5.000	4.975	4.973
HCC046	Chronic Pancreatitis	4.008	3.806	3.686	3.681	3.682
HCC047	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.	2.028	1.869	1.761	1.675	1.664
HCC048	Inflammatory Bowel Disease	2.185	2.010	1.877	1.774	1.760
HCC054	Necrotizing Fasciitis	5.280	5.093	4.966	4.966	4.966
HCC055	Bone/Joint/Muscle Infections/Necrosis.	5.280	5.093	4.966	4.966	4.966
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders.	3.170	2.968	2.818	2.754	2.746
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders.	0.803	0.689	0.591	0.473	0.457
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies.	2.651	2.462	2.325	2.244	2.234
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders.	2.651	2.462	2.325	2.244	2.234
HCC063	Cleft Lip/Cleft Palate	1.841	1.676	1.561	1.476	1.467
HCC066	Hemophilia	60.165	59.790	59.521	59.527	59.526
HCC067	Myelodysplastic Syndromes and Myelofibrosis.	11.585	11.458	11.370	11.361	11.360
HCC068	Aplastic Anemia	11.585	11.458	11.370	11.361	11.360
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.	7.073	6.964	6.883	6.847	6.842
HCC070	Sickle Cell Anemia (Hb-SS)	7.073	6.964	6.883	6.847	6.842
HCC071	Thalassemia Major	7.073	6.964	6.883	6.847	6.842

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC073	Combined and Other Severe Immunodeficiencies.	4.606	4.478	4.394	4.381	4.379
HCC074	Disorders of the Immune Mechanism	4.606	4.478	4.394	4.381	4.379
HCC075	Coagulation Defects and Other Specified Hematological Disorders.	2.791	2.702	2.634	2.596	2.591
HCC081	Drug Psychosis	3.438	3.202	3.033	2.892	2.872
HCC082	Drug Dependence	3.438	3.202	3.033	2.892	2.872
HCC087	Schizophrenia	2.827	2.586	2.422	2.311	2.298
HCC088	Major Depressive and Bipolar Disorders.	1.602	1.438	1.313	1.184	1.167
HCC089	Reactive and Unspecified Psychosis, Delusional Disorders.	1.589	1.433	1.312	1.183	1.165
HCC090	Personality Disorders	1.115	0.998	0.889	0.759	0.742
HCC094	Anorexia/Bulimia Nervosa	2.535	2.370	2.245	2.164	2.152
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.	5.275	5.178	5.108	5.049	5.040
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	1.351	1.255	1.177	1.105	1.096
HCC102	Autistic Disorder	1.127	1.009	0.899	0.771	0.754
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder.	1.115	0.998	0.889	0.759	0.742
HCC106	Traumatic Complete Lesion Cervical Spinal Cord.	10.383	10.248	10.157	10.135	10.131
HCC107	Quadriplegia	10.383	10.248	10.157	10.135	10.131
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord.	7.512	7.355	7.247	7.209	7.203
HCC109	Paraplegia	7.512	7.355	7.247	7.209	7.203
HCC110	Spinal Cord Disorders/Injuries	5.070	4.849	4.700	4.653	4.647
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.	1.804	1.606	1.474	1.372	1.360
HCC112	Quadriplegic Cerebral Palsy	0.073	0.036	0.009	0.000	0.000
HCC113	Cerebral Palsy, Except Quadriplegic	0.073	0.036	0.009	0.000	0.000
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	0.544	0.452	0.392	0.341	0.335
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.301	5.172	5.088	5.074	5.072
HCC117	Muscular Dystrophy	1.925	1.783	1.682	1.581	1.565
HCC118	Multiple Sclerosis	3.769	3.557	3.406	3.322	3.311
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	1.925	1.783	1.682	1.581	1.565
HCC120	Seizure Disorders and Convulsions	1.275	1.128	1.020	0.917	0.904
HCC121	Hydrocephalus	6.490	6.383	6.303	6.282	6.279
HCC122	Non-Traumatic Coma, and Brain Compression/Anoxic Damage.	8.031	7.885	7.780	7.766	7.763
HCC125	Respirator Dependence/Tracheostomy Status.	24.882	24.831	24.794	24.883	24.894
HCC126	Respiratory Arrest	7.394	7.224	7.123	7.191	7.202
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	7.394	7.224	7.123	7.191	7.202
HCC128	Heart Assistive Device/Artificial Heart	27.608	27.411	27.286	27.322	27.328
HCC129	Heart Transplant	27.608	27.411	27.286	27.322	27.328
HCC130	Congestive Heart Failure	2.607	2.505	2.437	2.423	2.422
HCC131	Acute Myocardial Infarction	7.214	6.923	6.738	6.797	6.807
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease.	4.822	4.534	4.368	4.345	4.345
HCC135	Heart Infection/Inflammation, Except Rheumatic.	5.503	5.383	5.302	5.271	5.268
HCC142	Specified Heart Arrhythmias	2.479	2.340	2.237	2.159	2.149
HCC145	Intracranial Hemorrhage	7.332	7.062	6.890	6.848	6.844
HCC146	Ischemic or Unspecified Stroke	1.907	1.754	1.666	1.624	1.620
HCC149	Cerebral Aneurysm and Arteriovenous Malformation.	2.765	2.588	2.468	2.389	2.378
HCC150	Hemiplegia/Hemiparesis	4.362	4.253	4.188	4.232	4.240

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC151	Monoplegia, Other Paralytic Syndromes.	2.821	2.693	2.606	2.557	2.551
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene.	8.986	8.890	8.830	8.913	8.926
HCC154	Vascular Disease with Complications	6.374	6.218	6.114	6.091	6.088
HCC156	Pulmonary Embolism and Deep Vein Thrombosis.	3.333	3.184	3.082	3.013	3.004
HCC158	Lung Transplant Status/Complications.	22.628	22.505	22.423	22.495	22.505
HCC159	Cystic Fibrosis	6.673	6.414	6.226	6.203	6.200
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.	0.867	0.759	0.665	0.564	0.551
HCC161	Asthma	0.867	0.759	0.665	0.564	0.551
HCC162	Fibrosis of Lung and Other Lung Disorders.	1.918	1.813	1.742	1.688	1.680
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.343	6.311	6.288	6.291	6.292
HCC183	Kidney Transplant Status	6.355	6.161	6.035	5.970	5.965
HCC184	End Stage Renal Disease	25.179	24.922	24.750	24.897	24.939
HCC187	Chronic Kidney Disease, Stage 5	1.067	1.016	0.985	0.997	1.001
HCC188	Chronic Kidney Disease, Stage 4	1.067	1.016	0.985	0.997	1.001
HCC203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism.	1.003	0.868	0.740	0.542	0.512
HCC204	Miscarriage with Complications	1.003	0.868	0.740	0.542	0.512
HCC205	Miscarriage with No or Minor Complications.	1.003	0.868	0.740	0.542	0.512
HCC207	Completed Pregnancy With Major Complications.	3.296	2.892	2.678	2.344	2.301
HCC208	Completed Pregnancy With Complications.	3.296	2.892	2.678	2.344	2.301
HCC209	Completed Pregnancy with No or Minor Complications.	3.296	2.892	2.678	2.344	2.301
HCC217	Chronic Ulcer of Skin, Except Pressure.	1.908	1.800	1.730	1.702	1.700
HCC226	Hip Fractures and Pathological Vertebral or Humerus Fractures.	8.274	8.044	7.894	7.911	7.913
HCC227	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.	4.796	4.648	4.546	4.494	4.488
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications.	24.793	24.786	24.778	24.810	24.814
HCC253	Artificial Openings for Feeding or Elimination.	7.812	7.725	7.666	7.696	7.700
HCC254	Amputation Status, Lower Limb/Amputation Complications.	3.011	2.887	2.811	2.821	2.823

Interaction Factors

SEVERE x HCC006.	Severe illness x Opportunistic Infections.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC008.	Severe illness x Metastatic Cancer ...	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC009.	Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC010.	Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC115.	Severe illness x Myasthenia Gravis/ Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC135.	Severe illness x Heart Infection/Inflammation, Except Rheumatic.	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC145.	Severe illness x Intracranial Hemorrhage.	7.044	7.251	7.387	7.555	7.575
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).	7.044	7.251	7.387	7.555	7.575

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
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).	7.044	7.251	7.387	7.555	7.575
SEVERE x HCC035.	Severe illness x End-Stage Liver Disease.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC038.	Severe illness x Acute Liver Failure/ Disease, Including Neonatal Hepatitis.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC153.	Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC154.	Severe illness x Vascular Disease with Complications.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC163.	Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	0.873	0.935	0.977	1.119	1.136
SEVERE x HCC253.	Severe illness x Artificial Openings for Feeding or Elimination.	0.873	0.935	0.977	1.119	1.136
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).	0.873	0.935	0.977	1.119	1.136

Enrollment Duration Factors

1 month of enrollment	0.316	0.276	0.247	0.232	0.230
2 months of enrollment	0.302	0.263	0.234	0.219	0.218
3 months of enrollment	0.278	0.241	0.213	0.199	0.197
4 months of enrollment	0.241	0.208	0.179	0.165	0.164
5 months of enrollment	0.217	0.188	0.162	0.148	0.147
6 months of enrollment	0.185	0.160	0.137	0.123	0.122
7 months of enrollment	0.152	0.131	0.111	0.099	0.098
8 months of enrollment	0.118	0.103	0.088	0.079	0.078
9 months of enrollment	0.074	0.064	0.054	0.048	0.048
10 months of enrollment	0.035	0.032	0.030	0.029	0.029
11 months of enrollment	0.030	0.028	0.027	0.027	0.027

Prescription Drug Factors

RXC 01	Anti-HIV Agents	6.528	5.936	5.505	5.164	5.120
RXC 02	Anti-Hepatitis C (HCV) Agents	8.369	7.752	7.359	7.413	7.430
RXC 03	Antiarrhythmics	0.116	0.112	0.109	0.096	0.090
RXC 04	Phosphate Binders	1.927	1.924	1.918	1.904	1.862
RXC 05	Inflammatory Bowel Disease Agents	1.746	1.591	1.470	1.293	1.266
RXC 06	Insulin	1.796	1.630	1.453	1.254	1.227
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only.	0.644	0.547	0.452	0.315	0.296
RXC 08	Multiple Sclerosis Agents	18.819	17.877	17.252	17.101	17.067
RXC 09	Immune Suppressants and Immunomodulators.	12.688	12.085	11.697	11.770	11.783
RXC 10	Cystic Fibrosis Agents	12.240	11.876	11.659	11.708	11.717
RXC 01 x HCC001.	Additional effect for enrollees with RXC 01 (Anti-HIV Agents) and HCC 001 (HIV/AIDS).	0.273	0.520	0.735	1.187	1.247
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)).	-0.156	0.043	0.168	0.300	0.311
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

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
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)).	-0.820	-0.761	-0.692	-0.635	-0.626
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)).	0.289	0.247	0.309	0.355	0.360
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)).	-0.303	-0.259	-0.209	-0.169	-0.164
RXC 08 x HCC118.	Additional effect for enrollees with RxC 08 (Multiple Sclerosis Agents) and HCC 118 (Multiple Sclerosis).	-1.409	-0.898	-0.556	-0.216	-0.157
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)).	0.536	0.652	0.731	0.831	0.844
RXC 09 x HCC056.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders).	-3.170	-2.968	-2.818	-2.754	-2.746
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).	-0.803	-0.689	-0.545	-0.428	-0.411
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)).	-0.783	-0.621	-0.528	-0.439	-0.427
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)).	38.322	38.485	38.558	38.691	38.706

TABLE 2—HHS HCCs IN THE SEVERITY ILLNESS INDICATOR VARIABLE

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

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.201	0.156	0.105	0.060	0.054
Age 5–9, Male	0.141	0.105	0.064	0.031	0.028
Age 10–14, Male	0.178	0.141	0.094	0.058	0.055
Age 15–20, Male	0.231	0.186	0.132	0.084	0.079
Age 2–4, Female	0.153	0.115	0.074	0.041	0.037
Age 5–9, Female	0.097	0.068	0.034	0.009	0.008
Age 10–14, Female	0.169	0.133	0.090	0.058	0.055
Age 15–20, Female	0.251	0.197	0.130	0.069	0.063
Diagnosis Factors					
HIV/AIDS	4.444	4.000	3.704	3.571	3.553
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	12.684	12.483	12.370	12.357	12.358
Central Nervous System Infections, Except Viral Meningitis	7.639	7.474	7.370	7.375	7.376
Viral or Unspecified Meningitis	3.537	3.306	3.162	2.985	2.961
Opportunistic Infections	14.897	14.855	14.821	14.803	14.798
Metastatic Cancer	33.549	33.307	33.125	33.137	33.137
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.316	9.063	8.873	8.780	8.769
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	7.430	7.181	6.996	6.883	6.868
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.288	3.116	2.980	2.862	2.844
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.288	3.116	2.980	2.862	2.844
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	0.971	0.848	0.742	0.624	0.608
Pancreas Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
Diabetes with Acute Complications	2.562	2.227	2.024	1.732	1.695
Diabetes with Chronic Complications	2.562	2.227	2.024	1.732	1.695
Diabetes without Complication	2.562	2.227	2.024	1.732	1.695
Protein-Calorie Malnutrition	13.857	13.753	13.679	13.719	13.724
Mucopolysaccharidosis	6.541	6.316	6.146	6.097	6.090
Lipidoses and Glycogenosis	6.541	6.316	6.146	6.097	6.090
Congenital Metabolic Disorders, Not Elsewhere Classified	6.541	6.316	6.146	6.097	6.090
Amyloidosis, Porphyria, and Other Metabolic Disorders	6.541	6.316	6.146	6.097	6.090
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.541	6.316	6.146	6.097	6.090
Liver Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
End-Stage Liver Disease	16.546	16.340	16.213	16.213	16.213
Cirrhosis of Liver	3.126	3.000	2.914	2.887	2.887
Chronic Viral Hepatitis C	2.946	2.800	2.696	2.677	2.679
Chronic Hepatitis, Other/Unspecified	0.565	0.486	0.438	0.412	0.409
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.172	11.066	11.000	11.024	11.029
Intestine Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.360	11.054	10.851	10.833	10.833
Intestinal Obstruction	4.422	4.220	4.069	3.964	3.951
Chronic Pancreatitis	12.558	12.300	12.130	12.111	12.111
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.280	2.164	2.067	1.971	1.957
Inflammatory Bowel Disease	7.491	7.076	6.790	6.672	6.656
Necrotizing Fasciitis	3.884	3.665	3.504	3.422	3.412
Bone/Joint/Muscle Infections/Necrosis	3.884	3.665	3.504	3.422	3.412
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.147	3.898	3.705	3.613	3.602

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.707	0.589	0.478	0.367	0.355
Osteogenesis Imperfecta and Other Osteodystrophies	1.308	1.197	1.101	1.020	1.009
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.308	1.197	1.101	1.020	1.009
Cleft Lip/Cleft Palate	1.309	1.130	0.998	0.869	0.853
Hemophilia	63.672	63.119	62.729	62.694	62.689
Myelodysplastic Syndromes and Myelofibrosis	14.847	14.726	14.643	14.617	14.613
Aplastic Anemia	14.847	14.726	14.643	14.617	14.613
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	6.690	6.486	6.338	6.255	6.246
Sickle Cell Anemia (Hb-SS)	6.690	6.486	6.338	6.255	6.246
Thalassemia Major	6.690	6.486	6.338	6.255	6.246
Combined and Other Severe Immunodeficiencies	5.228	5.082	4.975	4.916	4.908
Disorders of the Immune Mechanism	5.228	5.082	4.975	4.916	4.908
Coagulation Defects and Other Specified Hematological Disorders	4.562	4.439	4.341	4.263	4.253
Drug Psychosis	5.378	5.097	4.918	4.827	4.816
Drug Dependence	5.378	5.097	4.918	4.827	4.816
Schizophrenia	4.720	4.358	4.111	3.955	3.935
Major Depressive and Bipolar Disorders	2.523	2.294	2.112	1.933	1.909
Reactive and Unspecified Psychosis, Delusional Disorders	2.437	2.219	2.042	1.864	1.841
Personality Disorders	0.505	0.407	0.299	0.163	0.145
Anorexia/Bulimia Nervosa	2.473	2.274	2.118	2.023	2.009
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	1.577	1.426	1.324	1.254	1.244
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.523	1.376	1.270	1.181	1.169
Autistic Disorder	2.419	2.205	2.030	1.859	1.836
Pervasive Developmental Disorders, Except Autistic Disorder	0.522	0.436	0.337	0.218	0.203
Traumatic Complete Lesion Cervical Spinal Cord	9.975	9.927	9.898	9.978	9.989
Quadriplegia	9.975	9.927	9.898	9.978	9.989
Traumatic Complete Lesion Dorsal Spinal Cord	7.111	6.894	6.752	6.717	6.710
Paraplegia	7.111	6.894	6.752	6.717	6.710
Spinal Cord Disorders/Injuries	3.688	3.501	3.361	3.265	3.251
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	15.639	15.397	15.212	15.129	15.117
Quadriplegic Cerebral Palsy	2.136	1.935	1.829	1.823	1.824
Cerebral Palsy, Except Quadriplegic	0.189	0.141	0.109	0.080	0.076
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.317	1.190	1.100	1.029	1.020
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.492	10.315	10.194	10.192	10.192
Muscular Dystrophy	3.105	2.925	2.800	2.692	2.679
Multiple Sclerosis	9.585	9.204	8.943	8.908	8.904
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.105	2.925	2.800	2.692	2.679
Seizure Disorders and Convulsions	1.998	1.839	1.701	1.554	1.535
Hydrocephalus	4.263	4.146	4.066	4.043	4.041
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	5.460	5.327	5.226	5.177	5.170
Respirator Dependence/Tracheostomy Status	31.764	31.644	31.579	31.727	31.745
Respiratory Arrest	9.892	9.639	9.484	9.442	9.437
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	9.892	9.639	9.484	9.442	9.437
Heart Assistive Device/Artificial Heart	22.808	22.525	22.334	22.355	22.358
Heart Transplant	22.808	22.525	22.334	22.355	22.358
Congestive Heart Failure	5.721	5.612	5.528	5.484	5.477
Acute Myocardial Infarction	5.658	5.556	5.512	5.497	5.494
Unstable Angina and Other Acute Ischemic Heart Disease	4.360	4.255	4.196	4.165	4.163
Heart Infection/Inflammation, Except Rheumatic	12.103	11.996	11.921	11.912	11.912
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	3.989	3.841	3.696	3.585	3.569
Major Congenital Heart/Circulatory Disorders	1.271	1.172	1.054	0.940	0.927
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.828	0.738	0.638	0.551	0.541
Specified Heart Arrhythmias	3.678	3.514	3.378	3.301	3.291
Intracranial Hemorrhage	12.336	12.112	11.968	11.959	11.960
Ischemic or Unspecified Stroke	4.916	4.834	4.788	4.787	4.788
Cerebral Aneurysm and Arteriovenous Malformation	3.106	2.925	2.803	2.713	2.701

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Hemiplegia/Hemiparesis	4.229	4.100	4.016	3.960	3.952
Monoplegia, Other Paralytic Syndromes	2.907	2.753	2.650	2.591	2.582
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.094	11.845	11.673	11.607	11.596
Vascular Disease with Complications	11.883	11.747	11.650	11.669	11.670
Pulmonary Embolism and Deep Vein Thrombosis	15.067	14.952	14.883	14.915	14.920
Lung Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
Cystic Fibrosis	22.808	22.525	22.334	22.355	22.358
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.373	0.307	0.222	0.134	0.123
Asthma	0.373	0.307	0.222	0.134	0.123
Fibrosis of Lung and Other Lung Disorders	2.327	2.232	2.140	2.066	2.058
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.863	6.796	6.748	6.770	6.772
Kidney Transplant Status	10.610	10.344	10.176	10.122	10.115
End Stage Renal Disease	32.082	31.966	31.885	31.983	31.998
Chronic Kidney Disease, Stage 5	3.813	3.698	3.607	3.511	3.502
Chronic Kidney Disease, Severe (Stage 4)	3.813	3.698	3.607	3.511	3.502
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	0.929	0.782	0.635	0.417	0.386
Miscarriage with Complications	0.929	0.782	0.635	0.417	0.386
Miscarriage with No or Minor Complications	0.929	0.782	0.635	0.417	0.386
Completed Pregnancy With Major Complications	2.848	2.472	2.253	1.879	1.824
Completed Pregnancy With Complications	2.848	2.472	2.253	1.879	1.824
Completed Pregnancy with No or Minor Complications	2.848	2.472	2.253	1.879	1.824
Chronic Ulcer of Skin, Except Pressure	2.720	2.626	2.539	2.464	2.456
Hip Fractures and Pathological Vertebral or Humerus Fractures	6.385	6.075	5.850	5.736	5.724
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.954	1.797	1.655	1.504	1.483
Stem Cell, Including Bone Marrow, Transplant Status/Complications	22.808	22.525	22.334	22.355	22.358
Artificial Openings for Feeding or Elimination	11.222	11.090	11.022	11.127	11.143
Amputation Status, Lower Limb/Amputation Complications	5.244	4.993	4.817	4.689	4.670

TABLE 4—INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	242.262	240.657	239.483	239.461	239.461
Extremely Immature * Severity Level 4	148.994	147.251	145.979	145.799	145.783
Extremely Immature * Severity Level 3	34.940	33.753	32.859	32.577	32.555
Extremely Immature * Severity Level 2	34.940	33.753	32.859	32.577	32.555
Extremely Immature * Severity Level 1 (Lowest)	34.940	33.753	32.859	32.577	32.555
Immature * Severity Level 5 (Highest)	149.437	147.839	146.672	146.625	146.621
Immature * Severity Level 4	71.066	69.513	68.370	68.254	68.240
Immature * Severity Level 3	33.916	32.618	31.662	31.423	31.400
Immature * Severity Level 2	24.559	23.305	22.377	22.064	22.026
Immature * Severity Level 1 (Lowest)	24.559	23.305	22.377	22.064	22.026
Premature/Multiples * Severity Level 5 (Highest)	113.849	112.409	111.366	111.243	111.232
Premature/Multiples * Severity Level 4	26.707	25.337	24.357	24.088	24.061
Premature/Multiples * Severity Level 3	13.625	12.592	11.834	11.346	11.287
Premature/Multiples * Severity Level 2	8.285	7.520	6.882	6.224	6.128
Premature/Multiples * Severity Level 1 (Lowest)	5.381	4.835	4.284	3.704	3.632
Term * Severity Level 5 (Highest)	87.084	85.832	84.905	84.690	84.663
Term * Severity Level 4	13.879	12.979	12.323	11.859	11.806
Term * Severity Level 3	5.728	5.171	4.646	4.042	3.959
Term * Severity Level 2	3.614	3.188	2.691	2.051	1.970
Term * Severity Level 1 (Lowest)	1.596	1.375	0.973	0.579	0.544
Age1 * Severity Level 5 (Highest)	57.825	57.074	56.512	56.400	56.389
Age1 * Severity Level 4	10.546	10.003	9.561	9.255	9.219
Age1 * Severity Level 3	3.013	2.744	2.491	2.267	2.241
Age1 * Severity Level 2	1.880	1.673	1.452	1.219	1.191
Age1 * Severity Level 1 (Lowest)	0.515	0.455	0.374	0.314	0.307
Age 0 Male	0.646	0.595	0.560	0.489	0.478
Age 1 Male	0.120	0.106	0.093	0.073	0.070

TABLE 5—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 1000–1499 Grams.
Immature	Premature Newborns, Including Birth weight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birth weight 2000–2499 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 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC/description
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.
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.

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

Severity category	HCC/description
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.

v. Cost-Sharing Reduction Adjustments

We proposed to continue including an adjustment for the receipt of cost-sharing reductions (CSRs) in the risk adjustment models to account for increased plan liability due to increased utilization of health care services by enrollees receiving CSRs in all 50 states and the District of Columbia. For the 2020 benefit year, to maintain stability

and certainty for issuers, we proposed to maintain the CSR factors finalized in the 2019 Payment Notice.²⁸ See Table 7.

Consistent with the approach finalized in the 2017 Payment Notice,²⁹ we also proposed to continue to use CSR adjustment factors of 1.12 for all

Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have actuarial values above 94 percent. We are finalizing the CSR adjustment as proposed.

²⁸ See 83 FR 16930 at 16953.

²⁹ See 81 FR 12203 at 12228.

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT

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

Comment: Commenters supported the proposal that the CSR adjustments be consistent with those finalized in the 2019 Payment Notice. One commenter recommended that if HHS contemplates changing these factors for future benefit years, HHS should publish a white paper prior to rulemaking to provide issuers an advance opportunity to review and comment on the proposed approach. One commenter requested that HHS assess the impact of these factors and consider the possibility that issuers with a lower distribution of silver plan enrollees may be negatively impacted. One commenter supported continuing to use the CSR factor of 1.12 for Massachusetts’ wrap-around coverage.

Response: We are finalizing the CSR adjustment as proposed. We intend to continue to review the enrollee-level

EDGE data, including the distribution of enrollees by metal tier, to assess whether changes to these factors are needed. If we were to consider changes to the CSR adjustment in the future, we would do so through notice-and-comment rulemaking.

vi. Model Performance Statistics

To evaluate risk adjustment 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 also 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 will 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.³⁰ The final R-squared statistic for each model that is shown in Table 8 reflects the results from each dataset used in the separately solved models that are used to recalibrate the models for the 2020 benefit year, namely the 2015 MarketScan® data, and the 2016 and 2017 enrollee-level EDGE data.

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

Models	2016 Enrollee level EDGE data	2017 Enrollee-level EDGE data R-squared	2015 MarketScan® data R-squared
Platinum Adult	0.4189	0.4131	0.4120
Gold Adult	0.4131	0.4065	0.4065
Silver Adult	0.4084	0.4011	0.4023
Bronze Adult	0.4052	0.3974	0.3996
Catastrophic Adult	0.4047	0.3968	0.3991
Platinum Child	0.3109	0.3252	0.3330
Gold Child	0.3062	0.3201	0.3283
Silver Child	0.3022	0.3157	0.3244
Bronze Child	0.2986	0.3118	0.3207
Catastrophic Child	0.2981	0.3112	0.3201
Platinum Infant	0.3257	0.3168	0.3331
Gold Infant	0.3217	0.3127	0.3310

³⁰ Winkleman, Ross and Syed Mehmud. “A Comparative Analysis of Claims-Based Tools for

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

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

Models	2016 Enrollee level EDGE data	2017 Enrollee-level EDGE data R-squared	2015 MarketScan® data R-squared
Silver Infant	0.3188	0.3096	0.3297
Bronze Infant	0.3172	0.3079	0.3294
Catastrophic Infant	0.3170	0.3077	0.3294

b. Overview of the Risk Adjustment Transfer Methodology (§ 153.320)

We defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.³¹ The risk adjustment transfer methodology (state transfer formula payments and charges and high-cost risk pool payments and charges) is applied after issuers have completed their risk adjustment EDGE data submissions for the applicable benefit year. The state 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, we calculate separate transfer amounts for each rating area in which a risk adjustment covered plan operates).

The risk adjustment state payment 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 the plan can generate for those enrollees. These differences are then compared across plans in the state market risk pool and converted to a dollar amount based on the statewide average premium. HHS chose to use statewide average premium and normalize the risk adjustment state payment transfer formula to reflect state average factors so that each plan’s enrollment characteristics are compared to the state average and the calculated payment amounts equal calculated charges in each state market risk pool. Thus, each plan in the risk pool receives a risk adjustment payment or charge designed to compensate for risk for a plan with average risk in a budget-neutral manner. This approach supports the overall goals of the risk adjustment program, which are to encourage issuers to rate for the average risk in the

applicable state market risk pool, to stabilize premiums, and to avoid the creation of incentives for issuers to operate less efficiently, set higher prices, or develop benefit designs or create marketing strategies to avoid high-risk enrollees. Such incentives could arise if we used each issuer’s plan’s own premium in the risk adjustment state payment transfer formula, instead of statewide average premium.

In the absence of additional funding, we established through notice-and-comment rulemaking³² the HHS-operated risk adjustment program as a budget-neutral program to provide certainty to issuers regarding risk adjustment payments and charges, which allows issuers 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. Additionally, in establishing the HHS-operated risk adjustment program, we could not have relied on the potential availability of general appropriation funds without creating the same 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 process also would have required us to delay setting the parameters for any risk adjustment payment proration rates until well after the plans were in effect for the applicable benefit year. HHS also could

³² For example, see 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 the 2014 Payment Notice, Final Rule, 78 FR 15441 (March 11, 2013). Also see, the 2018 Payment Notice, Final Rule, 81 FR 94058 (December 22, 2016); and the 2019 Payment Notice, Final Rule, 83 FR 16930 (April 17, 2018). Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (December 10, 2018).

not have relied on any potential state budget appropriations in states that elected to operate a state-based risk adjustment program, as such funds would not be available for purposes of administering the HHS-operated risk adjustment program. Without the adoption of a budget-neutral framework, HHS would need to assess a charge or otherwise collect additional funds to avoid prorating risk adjustment payments. The resulting uncertainty would have also conflicted 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.

In light of the budget-neutral framework, HHS uses statewide average premium as the cost-scaling factor in the state payment transfer formula under the HHS-operated risk adjustment methodology, rather than a different parameter, such as each plan’s own premium, which would not have automatically achieved equality between risk adjustment payments and charges in each benefit year. As set forth in prior discussions,³³ use of a plan’s own premium or a similar parameter would have required a balancing adjustment in light of the program’s need for budget neutrality—either through reducing payments to issuers owed a payment, increasing charges on issuers assessed a charge, or splitting the difference in some fashion between issuers owed payments and issuers assessed charges. Such adjustments would have impaired the risk adjustment program’s goals of encouraging issuers to rate for the average risk in the applicable state market risk pool, stabilizing premiums, and avoiding the creation of incentives

³³ For example, see September 12, 2011, *Risk Adjustment Implementation Issues* White Paper, available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/riskadjustment_whitepaper_web.pdf. Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (December 10, 2018).

³¹ The state payment transfer formula refers to the part of the HHS risk adjustment methodology that calculates payments and charges prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year.

for issuers to operate less efficiently, set higher prices, develop benefit designs or create marketing strategies to avoid higher-risk enrollees. Adoption of a methodology that would require use of an after-the-fact balancing adjustment is also less predictable for issuers than a methodology that is established in advance of a benefit year. Stakeholders who support use of a plan's own premium state that use of statewide average premium penalizes issuers with efficient care management. While effective care management may make a plan more likely to have lower costs,³⁴ we do not believe that care management strategies make the plan more likely to enroll lower-than-average risk enrollees; effective care management strategies might even make the plan more likely to attract higher-than-average risk enrollees, in which case the plan will benefit from the use of statewide average premium in the state payment transfer formula in the HHS risk adjustment methodology. As noted by commenters to the 2014 Payment Notice proposed rule, transfers may also be more volatile from year to year and sensitive to anomalous premiums if scaled to a plan's own premium instead of the statewide average premium. In all, the advantages of using statewide average premium outweigh the pricing instability and other challenges associated with calculating transfers based on a plan's own premium.

In the HHS risk adjustment transfer methodology, the state payment transfer formula is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the state payment transfer formula is multiplied by each plan's total billable member months for the applicable benefit year to determine the payment due to or charge owed by the issuer for that plan in a rating area. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

Although we did not seek comment on this topic, we summarize and respond to the comments on statewide average premium and plan's own premium received in response to the proposed rule below. Given the volume of exhibits, court filings, white papers (including all corresponding exhibits), and comments on other rulemakings incorporated by reference, we are not able to separately address each of those documents. Instead, we summarize and

respond to the significant comments and issues raised by the commenters that are within the scope of this rulemaking.

Comment: Some commenters expressed support for the operation of the HHS risk adjustment program in a budget-neutral manner and the utilization of statewide average premium as the cost-scaling factor to ensure that issuers' collection amounts equal payment amounts for the applicable benefit year. These commenters noted that use of statewide average premium results in balanced payment transfers in a state market risk pool and helps advance the market stabilizing goals of the risk adjustment program, and they supported maintaining the current risk adjustment state payment transfer formula and the budget neutral framework.

Some commenters opposed the use of statewide average premiums. These commenters stated that the current risk adjustment state payment transfer formula's use of statewide average premiums penalizes efficient plans, and is a biased estimate of enrollee medical costs and actuarial risk that perversely penalize efficient, high-performing issuers. These commenters requested that HHS adopt alternatives to the existing risk adjustment methodology. One commenter supported the use of each plan's own premium as the cost scaling factor. This commenter stated that the risk adjustment state payment transfer formula does not need to operate as budget neutral, as section 1343 of the PPACA does not require that the program be budget neutral, and funds are available to HHS for the risk adjustment program from the CMS Program Management account to offset any potential shortfalls. The commenter also disagreed with HHS' rationale for using statewide average premium to achieve budget neutrality, and stated that even if budget neutrality is required, any risk adjustment payment shortfalls that may result from using a plan's own premium in the state payment transfer formula could be addressed through pro rata adjustments to risk adjustment transfers. This commenter further stated that use of statewide average premium is not predictable for issuers trying to set rates and compared the predicted risk adjustment results issuers set out in their respective rate filings with HHS' published actual risk adjustment results for a state, concluding that the risk adjustment program is failing to achieve its goal because its analysis found that issuers are failing to accurately forecast their risk adjustment results in their rate filings.

Conversely, other commenters expressed concerns about alternatives to statewide average premium. One commenter specifically opposed using a plan's own premium stating that it would undermine the risk adjustment program, create incentives for issuers to avoid enrolling high-cost individuals, and would not automatically balance transfers to zero. This commenter noted that the PPACA's risk adjustment statute requires states, or HHS on behalf of the states, to assess a charge on plans with lower than the average actuarial risk in the state market risk pool, and to make payments to plans with higher than the average actuarial risk in the state market risk pool. This commenter also agreed that absent Congressional action to appropriate additional funds, the risk adjustment program must operate in a budget-neutral manner. Additionally, the commenter concurred that if HHS were to require states operating their own risk adjustment programs to operate the programs to cover any shortfall between collections and payments for a benefit year, HHS would be effectively imposing an unfunded mandate on states. This commenter noted that analyses by the American Academy of Actuaries and Oliver Wyman indicated that the risk adjustment program is working as intended by compensating issuers that enroll higher-than-average risk enrollees and protecting against adverse selection.

Response: We agree that the use of statewide average premium supports the underlying goals of the risk adjustment program by discouraging the creation of benefit designs and marketing strategies to avoid high-risk enrollees and promoting market stability and predictability. The benefits of using statewide average premium as the cost scaling factor in the HHS risk adjustment state payment transfer formula therefore extend beyond its role in maintaining the budget neutrality of the program. Consistent with the statute, under the HHS-operated risk adjustment program, each risk adjustment covered plan in the state market risk pool receives a risk adjustment payment or owes a charge based on the plan's risk compared to the average risk in the state market risk pool. The statewide average premium reflects the average cost and efficiency level and was chosen as the cost scaling factor in the state payment transfer formula under the HHS-operated risk adjustment methodology for a number of reasons. More specifically, HHS chose to use statewide average premium to encourage issuers to rate for the average risk, to automatically achieve equality between

³⁴ There are many reasons why an issuer could have lower-than-average premiums. For example, the low premium could be the result of efficiency, mispricing, a strategy to gain market share, or some combination thereof.

risk adjustment payments and charges in each benefit year, and to avoid the creation of incentives for issuers to operate less efficiently, set higher prices, or develop benefits designs or create marketing strategies to avoid high-risk enrollees. HHS considered and again declined in the 2018 and 2019 Payment Notices³⁵ and in the Adoption of the Methodology for the HHS-operated Permanent Risk Adjustment Program for the 2017 Benefit Year Final Rule (2017 Risk Adjustment Final Rule)³⁶ and Adoption of the Methodology for the HHS-operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule (2018 Risk Adjustment Final Rule)³⁷ to adopt the use of each plan's own premium in the state payment transfer formula.

As we detailed in the 2018 Payment Notice and the 2017 and 2018 Risk Adjustment Final Rules,³⁸ use of a plan's own premium would likely lead to substantial volatility in transfer results, and could result in even higher transfer charges for low-risk, low-premium plans because of the program's budget neutral framework. In addition, use of plan's own premium in a budget neutral program would require even greater transfer payments to high-risk, high-premium plans. Furthermore, use of a plan's own premium in the HHS formula would actually disadvantage high-risk, low-premium plans, or plans that some commenters referred to as the "efficient plans," by undercompensating them based on their lower average premiums, which, in turn, could incentivize such plans to inflate premium prices to receive more favorable risk adjustment transfers along with increased premium revenue. If HHS instead applied a balancing adjustment to the state payment transfer formula in favor of these plans, low-risk, low-premium plans would be required to pay an even higher percentage of their plan-specific premiums in risk adjustment transfer charges due to the need to maintain the program's budget neutrality. This type of balancing adjustment would also result in a reduction to payments to high-risk, low-premium plans that are presumably more efficient than high-risk, high-premium plans, further incentivizing such plans to inflate premiums as described above. In other words, the use of a plan's own premium in the HHS program would neither reduce risk adjustment charges for low-cost and

low-risk issuers, nor would it incentivize issuers to operate at the average efficiency. The application of a balancing adjustment in favor of low-risk, low-premium plans could undercompensate high-risk plans, increasing the likelihood that such plans would raise premiums. In addition, if the application of a balancing adjustment was split equally between high-risk and low-risk plans, such an adjustment would incentivize issuers to increase premiums or to employ risk-avoidance techniques. Finally, any such balancing adjustments would have to be determined after state transfers had been calculated, because an approach that uses the plan's own premium to calculate transfers would not necessarily result in budget-neutral transfers without a separate after-the-fact adjustment. As detailed above, such after-the-fact adjustments would impair the goals of the risk adjustment program and be less predictable for issuers. For all of these reasons, we previously declined and continue to decline to use each plan's own premium and are maintaining use of statewide average premium as the cost-scaling factor in the state payment transfer formula.

Comments: One commenter requested that HHS include a care management factor in the risk adjustment methodology, such as the care management effectiveness index (CME index) developed by Axene Health Partners, as this commenter believed that a care coordination factor would mitigate the impact of using statewide average premiums for issuers that successfully perform care management and improve health. This commenter stated that HHS represented in previous rulemaking that it could consider using the CME index in future years and encouraged HHS to follow through on that promise. Another commenter requested that HHS explore how plans with low administrative costs or high quality scores based on objective criteria and high-performing networks could be rewarded. One commenter stated that HHS' position in the proposed rule that it did "not believe that the care management strategies make the plan more likely to enroll lower-than-average risk enrollees; effective care management strategies might even make the plan more likely to attract higher-than-average risk enrollees, in which case the plan would benefit from the use of statewide average premium in the state payment transfer formula in the HHS risk adjustment methodology" was based on a faulty premise. This commenter stated that, in addition to care management strategies, the breadth

of the plan's provider network has significant impact on price, and that, through the state payment transfer formula, enrollees who choose narrow networks subsidize plans from dominant issuers that can tend to have larger networks and higher prices. This commenter viewed this as a detrimental effect of the state payment transfer formula on plans with enrollees that choose narrow networks.

Some comments suggested proposed improvements to the HHS risk adjustment program generally. A few commenters expressed a desire for broad risk adjustment changes, including an exemption for new and fast-growing plans from risk adjustment for 3 to 5 years, applying a credibility-based approach to participation in risk adjustment based on membership size or market share, and placing an upper bound on the amount of a plan's risk adjustment transfer charge or using two-stage adult models that HHS proposed in the 2018 Payment Notice proposed rule. One commenter suggested HHS look at steps some states have taken to correct market distortions and consider the possibility of incorporating similar changes into the HHS risk adjustment models and state payment transfer formula. One commenter noted that HHS is aware of risk adjustment bias, has acknowledged its distortion, and has ignored the "fix" to switch the risk scores that were used by HHS with risk scores that more accurately represent the actual HCC costs or adopt another model that would eliminate estimated bias. This commenter also suggested HHS give states the option, at their discretion, to use a graduated cap on risk adjustment charges to reduce volatility and increase predictability of results, to establish a cap based on a percentage of premium to protect small issuers from the impact of large risk adjustment charges, or to allow states to consider structures in which caps shift at smaller more graduated intervals based on issuer size, to lower the risk that small enrollment shifts will tip an issuer between various caps.

Response: We appreciate the feedback on proposed updates to the HHS risk adjustment program. As we have noted, we remain committed to evaluating the program and engaging stakeholders in the program's policy development. We continue to regularly assess whether the HHS-operated risk adjustment program should be modified based on analysis of more recent data and changes (if any) in market dynamics, while weighing the tradeoffs of refinements with continuing to provide stability and predictability. Throughout this rule, we have identified several specific risk adjustment topics

³⁵ 81 FR 94100 and 83 FR 16930.

³⁶ 83 FR 36456.

³⁷ 83 FR 63419.

³⁸ 81 FR at 94100; 83 FR at 36458; and 83 FR at 63425.

we are currently assessing, anticipate seeking stakeholder feedback on, and may contemplate changes for future benefit years through notice-and-comment rulemaking.

We continuously evaluate whether improvements are needed to the HHS risk adjustment methodology, and will continue to do so as additional years' data become available. For example, beginning with the 2018 benefit year, we adopted a 14 percent reduction to the statewide average premium to account for administrative costs that are unrelated to the claims risk of the enrollee population.³⁹ While low cost plans are not necessarily efficient plans,⁴⁰ we believe this adjustment differentiates between premiums that reflect savings resulting from administrative efficiency from premiums that reflect healthier-than-average enrollees. HHS also modified the risk adjustment methodology beginning with the 2018 benefit year by incorporating a high-cost risk pool adjustment to mitigate residual incentives for risk selection to avoid high-cost enrollees, to better account for the average risk associated with the factors used in the HHS risk adjustment models, and to ensure that the actuarial risk of a plan with high-cost enrollees is better reflected in transfers to issuers with high actuarial risk.⁴¹ Other recent changes made to the HHS risk adjustment program include the incorporation of a partial year adjustment factor and prescription drug utilization factors.⁴²

However, at this time, we decline to amend the risk adjustment methodology to include a CME index or a similar care coordination adjustment. As we previously noted,⁴³ a change of this magnitude requires significant study and evaluation. Although this type of change is not feasible at present, we will continue to examine the feasibility, specificity, and sensitivity of measuring care management effectiveness through enrollee-level EDGE data for the individual, small group, and merged markets, and the benefits of incorporating such measures in the HHS risk adjustment transfer methodology in future benefit years, either through future rulemaking or other opportunities in which the public can submit comments. We believe that a robust risk adjustment program encourages issuers to improve care management

effectiveness, as doing so would reduce plans' medical costs. As we explain above, use of statewide average premium in the HHS risk adjustment state payment transfer formula incentivizes plans to apply effective care management techniques to reduce losses, whereas use of a plan's own premium could be inflationary as it benefits plans with higher-than-average costs and premiums. While effective care management may make a plan more likely to have lower costs and premiums, we do not believe that care management strategies necessarily make the plan more likely to enroll lower-than-average risk enrollees. As we noted in the proposed rule, implementation of effective care management strategies may particularly attract high-risk enrollees with complex conditions that incur repeat utilization of services.

In addition, there are many reasons why an issuer could have lower-than-average premiums. For example, the low premium could be the result of efficiency, mispricing, a strategy to gain market share, or some combination thereof. As such, we disagree with the comment that the risk adjustment state payment transfer formula unfairly results in enrollees that choose narrow networks subsidizing enrollees in broader networks, including enrollees in plans issued by dominant carriers. Networks are just one of many plan design characteristics that are captured through the use of the statewide average premium in the state payment transfer formula, which is designed to discourage the creation of plan designs and marketing strategies to avoid high-risk enrollees, in keeping with the goals of the risk adjustment program. Thus, to the extent certain plan network designs attract sicker-than-average enrollees, the risk adjustment program assesses the level of risk and compensates those plans for the incremental risk.

We have previously considered other model changes, including the adoption of a two-stage adult model. Specifically, as discussed in the 2018 Payment Notice proposed rule,⁴⁴ we considered the use of a constrained regression approach under which we would have estimated the adult risk adjustment model using only the age-sex variables. Under this approach, we would have then re-estimated the model using the full set of HCCs, while constraining the value of the age-sex coefficients to be the same as those from the first estimation. We also considered creating separate models for enrollees with and without HCCs to derive two separate sets of age-sex coefficients. We

evaluated the effect of these possible modifications, and ultimately decided to not move forward with such changes due to concerns of significantly undercompensating plans with higher-than-average actuarial risk.⁴⁵

We continue to evaluate ways to improve the risk prediction of the HHS risk adjustment models under various approaches to model estimation that might more precisely account for the non-linearities in plan liability as referenced in the 2016 Risk Adjustment White Paper.⁴⁶ We are continuing to investigate HCC count models whereby the number of an enrollee's HCCs would be considered in calculating an enrollee's risk score, similar to the proposed Medicare Advantage risk adjustment model incorporating HCC counts.⁴⁷ As another alternative, we are evaluating whether a non-linear term might improve the prediction of the models over the current linear model specification method for the adult models. For example, this non-linear method would include an additive term that is the sum of the risk score exponentiated to a factor solved by the models. The added non-linear term would be a measure of overall disease burden in which having combinations of HCCs can have a larger effect than the sum of the individual HCCs.

We continue to evaluate alternative modeling approaches while considering several important trade-offs between making improvements to risk prediction and the year-to-year predictability of the models. We also are examining any shortcomings of the potential alternatives that include additional complexity, lack of transparency, and potential upcoding incentives. For example, because issuers would receive an incremental additional factor for coding another HCC, there might be an incentive for upcoding, particularly with a count model. We believe that these alternative approaches require further investigation prior to making any of these types of changes to the models. For these reasons, we intend to solicit comments in the future on potential proposed improvements to the current models, as well as alternative modeling methods involving either non-linear or count models for potential use in future benefit years of HHS-operated

³⁹ 81 FR 94099.

⁴⁰ If a plan is a low-cost plan with low claims costs, it could be an indication of mispricing, as the issuer should be pricing for average risk.

⁴¹ See 81 FR 94080.

⁴² See 81 FR at 94071 and 94074.

⁴³ See 83 FR at 93425.

⁴⁴ 81 FR 61455 at 61473.

⁴⁵ 81 FR at 94083.

⁴⁶ Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

⁴⁷ Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model. December 20, 2018. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtg-SpecRateStats/Downloads/Advance2020Part1.pdf>.

risk adjustment model recalibration. We would especially be interested in comments regarding the factors HHS should consider in evaluating performance and their effects on subgroups in the population. We intend to also seek comment on the trade-offs we should consider, along with other risk adjustment topics.

Comment: One commenter requested that HHS reopen rulemaking proceedings, reconsider, and revise the Payment Notices for the 2017, 2018, and 2019 benefit years regarding the risk adjustment program under section 553(e) of the Administrative Procedure Act.

Response: The requests related to the 2017, 2018, and 2019 benefit year rulemakings are outside the scope of the proposed rule and this final rule, which is limited to the 2020 benefit year.

i. State Flexibility Requests (§ 153.320(d))

In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology, which is calibrated on a national dataset, for the state's individual, small group, or merged markets, by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's market(s). We finalized that any requests received will be published in the respective benefit year's proposed notice of benefit and payment parameters, and the supporting evidence for the request will be made available for public comment.⁴⁸

In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. If approved by HHS, state reduction requests will be applied to the plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation below).

We proposed to amend § 153.320(d)(3) to add language to provide that if the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d),

HHS will do so, making available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information. Similar to the rate review program established under section 2794 of the PHS Act, HHS would release only information that is not a trade secret or confidential commercial or financial information as defined under the HHS FOIA regulations.⁴⁹ In these circumstances, similar to the federal rate review requirements, we proposed that any states requesting a reduction provide a version for public release that redacts the trade secret and confidential commercial or financial information as defined under the HHS FOIA regulations, while also providing an unredacted version to HHS for its review of the state's reduction request. We also proposed that state requests for individual market risk adjustment transfer reductions would be applied to both the catastrophic and non-catastrophic individual market risk pools, unless state regulators request otherwise.

We are finalizing our amendment to § 153.320(d)(3) to add language to provide that if the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS FOIA regulations at 45 CFR 5.31(d), HHS will make available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence. In light of comments received, we are not finalizing our proposal to apply requests for individual market risk adjustment transfer reductions to both the catastrophic and non-catastrophic individual market risk pools within the state, unless the state requested otherwise.

For the 2020 benefit year, HHS received a request to reduce risk adjustment transfers for the Alabama small group market by 50 percent. Alabama's request states that the presence of a dominant carrier in the small group market precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the risk adjustment payment issuers' financial data suggested that any premium increase

resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2020 benefit year will not exceed 1 percent, the *de minimis* premium increase threshold. We sought comment on Alabama's request to reduce risk adjustment transfers in the small group market by 50 percent for the 2020 benefit year. The request and additional documentation submitted by Alabama was posted under the "State Flexibility Requests" heading at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html>. In light of our analysis of the information submitted with Alabama's request and the comments received, we are approving Alabama's request to reduce risk adjustment transfers in the small group market for the 2020 benefit year by 50 percent.

The following is a summary of the public comments we received on our proposals regarding state flexibility requests under § 153.320(d), and on Alabama's 2020 benefit year reduction request.

Comment: Commenters supported the ability of states to provide redacted versions of public-facing documents, although two raised questions about the scope of the redactions and whether the resulting documents would be sufficient to permit an effective review by interested parties.

Response: We are finalizing this amendment as proposed, as we believe it is important to protect information that contains trade secrets or confidential commercial or financial information within the meaning of the HHS FOIA regulations at § 5.31(d). However, we will seek to implement an approach with targeted redactions focused on information that would be considered trade secrets or confidential commercial, or financial information under § 5.31(d), to support effective review by interested parties.

Comment: One commenter opposed the application of state individual market risk adjustment transfer reduction requests to both the individual market catastrophic and non-catastrophic risk pools within the state. The commenter noted that the individual market catastrophic and non-catastrophic risk pools have different characteristics that impact the size of transfers.

Response: After consideration of the commenters' concerns, we are not finalizing the proposed default to extend a state individual market reduction request to adjust transfers in both the individual catastrophic and non-catastrophic risk pools, unless the

⁴⁸ 2019 Payment Notice Final Rule, 83 FR 16930 (April 17, 2018) and § 153.320(d)(3).

⁴⁹ See § 154.215(h)(2).

state regulators request otherwise. When a state submits a reduction request related to the individual market transfers under the HHS state payment transfer formula, it will need to outline the risk pools the request and analysis apply to as part of its submission under § 153.320(d)(1). We are amending the regulatory language at § 153.320(d) to specifically reference state market risk pools consistent with this approach and to make some technical edits.

Comment: The majority of comments about Alabama's state flexibility request expressed support for the state's request, with many stating that states are best equipped to evaluate the needs of their insurance markets. Commenters opposing this request pointed to the fact that states can elect to operate the PPACA risk adjustment program and propose their own risk adjustment methodology, or that the current HHS-operated risk adjustment methodology is operating as intended. Multiple commenters expressed concern regarding the methodology Alabama used to provide evidence supporting its request, each stating that a more thorough actuarial analysis was needed, and some pointed to the requested 50 percent reduction as a crude and blunt figure not based on data.

Response: We agree that states are best equipped to understand the needs of their insurance markets and in the 2019 Payment Notice, HHS provided the flexibility for these reduction requests when a state elects not to operate the PPACA risk adjustment program. For some states, an adjustment to transfers calculated by HHS under the state payment transfer formula may more precisely account for cost differences attributable to adverse selection in the respective state market pools. Further, allowing these adjustments can account for the effect of state-specific rules or unique market dynamics that may not be captured in the HHS methodology, which is calibrated on a national dataset, without the necessity

for states to undertake the burden and cost of operating their own PPACA risk adjustment program.

We reviewed Alabama's supporting evidence regarding the state's unique small group market dynamics that it believes warrant an adjustment to the HHS calculated risk adjustment small group market transfers for the 2020 benefit year. Alabama provided information demonstrating the presence of a dominant carrier in the small group market precludes the HHS-operated risk adjustment transfer methodology from working as precisely as it would with a more balanced distribution of market share. Alabama state regulators noted they do not assert that the HHS formula is flawed, only that it results in imprecise results in the state's small group market that could further reduce competition and increase costs for consumers. The state regulators also provided information demonstrating that the request would have a *de minimis* impact on necessary premium increase for payment issuers, consistent with § 153.320(d)(1)(iii). We note that HHS reviewed the unredacted state supporting analysis in evaluating Alabama's request, along with other data available to HHS. We found the supporting analysis submitted by Alabama to be sufficient in evaluating the market-specific circumstances validating Alabama's request.

Based on our review, we agree that any necessary premium increase for issuers likely to receive payments as a result of a 50 percent reduction to risk adjustment transfers in the Alabama small group market for the 2020 benefit year would not exceed 1 percent. HHS has determined that the state has demonstrated the existence of relevant state-specific factors that warrant an adjustment to more precisely account for relative risk differences and that the adjustment would have a *de minimis* effect. Therefore, we are approving Alabama's requested reduction under § 153.320(d)(4)(i)(B) based on the state

regulators' identification of unique state-specific factors in the Alabama small group market and the supporting analysis of a *de minimis* effect of the reduction requested. The 50 percent reduction will be applied to the 2020 benefit year plan PPM payment or charge transfer amount (T_i in the state payment transfer calculation below) for the Alabama small group market.

We also note that state regulators seeking a reduction to risk adjustment transfers in the state's individual catastrophic risk pool, individual non-catastrophic risk pool, small group market or a merged market for the 2021 benefit year should submit supporting materials to HHS as established under § 153.320(d). We will review any requests received on an annual basis, will make the supporting evidence publicly available for comment in the proposed notice of benefit and payment parameters for the respective benefit year, and will consider the relevant comments in our review of the state request for the applicable benefit year.

ii. The Risk Adjustment Transfer Methodology

Although the proposed HHS risk adjustment transfer methodology for the 2020 benefit year is unchanged from what was finalized in the 2019 Payment Notice (83 FR 16954 through 16961), we believe it is useful to republish the calculation in its entirety. Additionally, we are republishing the description of the administrative cost reduction to the statewide average premium and high-cost risk pool factors, although these factors and terms also remain unchanged in this final rule.⁵⁰ Transfers (payments and charges) under the state payment transfer formula 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 transfer methodology 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 will be summed across all risk adjustment covered plans in the risk pool in the market in the state.

The difference between the two premium estimates in the state payment transfer formula 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 will be assessed a charge or receive a payment—even if its risk score is greater than 1.0, it is possible that the plan will be assessed a charge if the premium

⁵⁰ See 83 FR 16930 at 16960.

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 under the state payment transfer formula are calculated at the state market risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment state payment transfer calculations.⁵¹ This resulting PMPM plan payment or charge will be multiplied by the number of billable member months to determine the plan's payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the state.

We defined the cost scaling factor, or the statewide average premium term, as the sum of the average premium per member month of plan *i* (P_i) multiplied by plan *i*'s share of statewide enrollment in the market risk pool (s_i). The statewide average premium will be adjusted to remove a portion of the administrative costs that do not vary with claims (14 percent) as follows:

$$\bar{P}_S = (\sum_i (s_i \cdot P_i)) * (1 - 0.14) = (\sum_i (s_i \cdot P_i)) * 0.86$$

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*.

The high-cost risk pool adjustment amount will be added to the state payment transfer formula 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 percentage 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 (TP_i). For this calculation, we will use a percent of premium adjustment factor that is applied to each plan's total premium amount.

The total plan transfers for a given benefit year will be calculated as the product of the plan PMPM's 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 transfer methodology for a benefit year will be calculated as follows:

$$\text{Total transfer}_i = (T_i \cdot M_i) + (HRP_i - (HRPC_m \cdot TP_i))$$

Where:

Total Transfer_i = Plan *i*'s total HHS risk adjustment program transfer amount;
 T_i = Plan *i*'s PMPM transfer amount based on the state transfer calculation;
 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*;
 TP_i = Plan *i*'s total premium amounts.

As we noted above, we approved Alabama's small group market reduction request for the 2020 benefit year. The approved reduction percentage (50 percent) will be applied to the 2020 benefit year plan PMPM payment or charge transfer amount (T_i) under the state payment transfer calculation for the Alabama small group market risk pool. The Alabama reduction to the PMPM transfer amounts is not shown in the HHS risk adjustment state payment transfer formula above. While we note that we addressed comments regarding the high-cost risk pool transfer calculation in the high-cost risk pool section above and comments regarding the cost-scaling factor in the state payment transfer formula in the overview of the transfer methodology section above, the following is a summary of the other public comments we received on the total plan transfer calculation published in the proposed rule.

Comment: One commenter supported HHS reducing the statewide average premium to account for costs associated with administrative expenses that do not vary with claims. Another commenter recommended that HHS publish the analysis used to determine the 14 percent administrative expense factor, including the specific line items from the Medical Loss Ratio (MLR) Annual Reporting Form that were included as administrative expenses that do not vary with claims to determine the 14 percent reduction of premium.

Response: As detailed in the 2018 Payment Notice,⁵² to derive this parameter, we analyzed and categorized administrative and other non-claims expenses in the MLR Annual Reporting Form,⁵³ and estimated, by category, the

extent to which the expenses varied with claims. We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, netting out claims costs financed through cost-sharing reduction payments.⁵⁴ We compared these expenses to total costs, rather than directly to premiums, to ensure that the estimated administrative cost percentage was not distorted by under- or over-pricing during the years for which MLR data are available. Using this methodology, we determined that the mean administrative cost percentage is 14 percent. While we are assessing whether other data sources might be able to supplement this analysis for potential updates for future years, we continue to believe that the current percentage represents a reasonable percentage of administrative costs on which risk adjustment transfers should not be calculated.

c. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.710)

In the 2018 Payment Notice,⁵⁵ we finalized the collection of masked enrollee-level data from issuers' EDGE servers (referred to as "enrollee-level EDGE data") beginning with the 2016 benefit year to recalibrate the HHS risk adjustment models and inform development of the AV Calculator and methodology.

In the 2018 Payment Notice, we also stated that we would consider using this enrollee-level EDGE data in the future to calibrate other HHS programs in the individual and small group markets, and to produce a public use file to help governmental entities and independent researchers better understand these markets. We noted that a public use file derived from these data would be de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, would not include proprietary issuer or plan identifying data, and would adhere to HHS rules and policies regarding protected health information (PHI) and personally identifiable information (PII). We also described in guidance the data elements in the enrollee-level EDGE data set and

incurred, the federal and state taxes and licensing on regulatory fees, and other non-claims costs. We also assumed 25 percent of general administrative expenses, as reported on the MLR Annual Reporting Form would be included in the administrative cost parameter. Information on the medical loss ratio data are available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

⁵⁴ The analysis used 2016 CSR payment data.

⁵⁵ See 81 FR 94058 at 94101.

⁵¹ As detailed elsewhere in this final rule, catastrophic plans and non-catastrophic plans and merged market plans are considered part of the individual market for purposes of the national high-cost risk pool payment and charge calculations.

⁵² 81 FR 94100.

⁵³ To estimate the administrative cost parameter, we used information in the MLR Annual Reporting Form on health care quality improvement expenses

the data elements proposed to be made available for research requests.⁵⁶

Under the HIPAA safe harbor for de-identification of data at 45 CFR 164.514(b)(2), public use files are considered de-identified if they exclude 18 specific identifiers that could be used alone or in combination with other information to identify an individual who is a subject of the information. To make the enrollee-level EDGE data available as a public use file that comports with the requirements of § 164.514(b)(2), we would have to remove dates (other than the year) and ages for enrollees ages 90 or older,⁵⁷ and determine that the information could not be used alone or in combination with other information to identify an individual who is a subject of the information. Commenters stated that a public use file would be limited in its usefulness because it excludes dates that would be useful to conduct health services research. A limited data set, as defined at § 164.514(e)(2), may include dates, which could enable requestors to do analyses they would not be able to do with a public use file. In addition, under § 164.514(e)(4), a limited data set recipient must enter into a data use agreement that establishes the permitted uses or disclosures of the information and prohibits the recipient from identifying the information. We believe entities seeking to use the enrollee-level EDGE data will be able to better understand the individual and small group markets with a limited data set.

Thus, in the proposed rule, we proposed to create and make available by request a limited data set file rather than a public use file, as we believe a limited data set file will be more useful to requestors for research, public health, or health care operations purposes. We noted that, under this proposal, we would make enrollee-level EDGE data, beginning with the 2016 benefit year, available as a “limited data set” file under § 164.514(e). This limited data set file would not include the direct identifiers of the individual or of relatives, employers, or household members of the individual, which are required to be removed under the limited data set definition at § 164.514(e)(2) and which issuers do not submit to their EDGE servers. We also proposed to limit disclosures of the limited data set to requestors who seek these data for research, public health, or

health care operations purposes, as those terms are defined under § 164.501. We stated that we would require qualified requestors to sign a data use agreement to ensure these data will be maintained, used, and disclosed only as permitted under the HIPAA Privacy Rule, and to ensure that any inappropriate uses or disclosures are reported to HHS. We noted that HHS components would also be able to request the limited data set file for research, public health, or health care operations purposes, as those terms are defined under § 164.501. We also clarified that, if the proposal is finalized, we would make a limited data set file available on an annual basis, reflecting enrollee-level data from the most recent benefit year available on EDGE servers. We stated that if we finalize the proposal to make a limited data set file available, HHS would not offer a public use file based on the enrollee-level EDGE data. We sought comment on this proposal.

In addition, we explained in the proposed rule that we received feedback in response to the guidance describing the data elements to be made available as part of the public use file for research requests⁵⁸ noting that researchers would benefit from additional data elements on enrollees’ geographic identifiers, enrollees’ income level, provider identifier, provider’s geographic location, hashed claim identifier, enrollees’ plan benefit design details, and enrollees’ out-of-pocket costs by cost-sharing type (deductible, coinsurance, and copayment). We noted that we began collecting a claim identifier⁵⁹ to associate all services rendered under the same claim beginning with the 2017 benefit year enrollee-level EDGE data. Therefore, we stated that if we were to finalize the limited data set proposal, we would be able to include this grouped claims identifier beginning for the 2017 benefit year enrollee-level EDGE limited data set file. However, regarding the other data elements commenters requested, we explained that either issuers do not submit them to their EDGE servers, or we currently do not extract them from

⁵⁸ Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollee-level-EDGE-Dataset-for-Research-Requests-05-18-18.pdf>.

⁵⁹ For the 2017 benefit year, we have included a unique claim identifier field, a hashed claim identifier, in the data extract. The claim identifier is a random hashed number assigned for each set of service line items associated with each claim, and cannot be used to identify the enrollee, plan or medical record. Including this claim identifier will allow data users to associate all service line items rendered under the same claim and also permit more rigorous checks of data quality.

issuers’ EDGE servers due to concerns about the ability to use the data element(s) to identify issuers or plans. For example, issuers do not currently submit data to their EDGE servers on enrollees’ plan benefit design, specific cost-sharing elements (deductibles, copayments), provider identifiers, providers’ geographic location, enrollees’ income level, or enrollees’ geographic location more specific than the rating area, and therefore, we are unable to extract such information as part of the enrollee-level EDGE data. However, issuers do submit enrollees’ state and rating areas as part of the EDGE server submissions, making it possible to extract these data elements from the issuers’ EDGE servers as part of the enrollee-level EDGE data. We stated in the proposed rule that, if we were to extract state and rating area data elements, we could also make such information available as part of the proposed enrollee-level EDGE limited data set file. We stated in the proposed rule that we continue to believe the enrollee-level EDGE data can increase cost transparency for consumers and stakeholders for the individual and small group markets, and can be a useful resource for government entities and independent researchers to better understand these markets. We also recognized access and use of enrollee-level EDGE data should continue to safeguard enrollees’ privacy and security and issuers’ proprietary information. We reiterated that we use the enrollee-level EDGE data to recalibrate the HHS risk adjustment models and inform development of the AV Calculator and methodology and stated that extracting additional state and rating area information could enable HHS to assess the impact of differences in geographic factors in the HHS risk adjustment methodology. In addition, we stated that stakeholders have noted that adding geographic elements to the AV Calculator would better estimate the AV of plans based on the cost differences across regions. Extraction of these geographic details (state and rating area) from issuers’ EDGE servers could also help support other HHS programs and policy priorities, as well as provide additional data elements for researchers. We noted that although these geographic data elements are not currently extracted from the enrollee-level EDGE data set, extracting them would not increase burden for issuers, as issuers already submit these data elements as part of the EDGE server data submission process. We stated in the proposed rule that if we were to extract state and rating area

⁵⁶ Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollee-level-EDGE-Dataset-for-Research-Requests-05-18-18.pdf>.

⁵⁷ HHS does not currently collect any of the other data elements under § 164.514(b)(2) that would require de-identification.

information, we would do so as part of the enrollee-level EDGE data extraction and would use this information to support the recalibration and policy development related to the HHS-operated risk adjustment program, the AV Calculator and methodology, as well as other HHS programs in the individual and small group (including merged) markets. We sought comment on whether to extract state and rating area information for enrollees as part of the enrollee-level EDGE data. We also sought comment on how state and rating area information could be used in the HHS-operated risk adjustment program, AV Calculator and methodology, and other HHS programs in the individual and small group (including merged) markets, as well as on how these data elements could benefit researchers and public health. We sought comment on, if we were to extract these data elements, whether to make state and rating area information available as part of the proposed limited data set file that would be made available to qualified requestors. We sought comment on the advantages and disadvantages of using state and rating area information for recalibration of the HHS-operated risk adjustment program, the AV Calculator and methodology, and other HHS individual and small group (including merged) market programs. In addition, we sought specific comment on possible research purposes for these data elements, whether the benefits of extracting these additional data elements outweigh the potential risk to issuers' proprietary information, and whether extraction of these data elements is consistent with the goals of a distributed data environment.

We also sought specific comment on the other data elements outlined in the proposed rule that commenters requested be part of the enrollee-level EDGE dataset, but that issuers do not currently submit to their EDGE servers (for example, enrollees' income level, provider identifier, provider's geographic location, hashed claim identifier,⁶⁰ enrollees' plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type, such as deductible, coinsurance, and copayment), and other enrollment and claims data elements not otherwise described in the proposed rule, and whether collection of such data elements could benefit the calibration of the HHS risk adjustment program, the

AV calculator and methodology, and other HHS individual and small group (including merged) market programs. We also sought specific comment with examples on whether other data elements that issuers do not currently submit to their EDGE servers could benefit further research, public health, or health care operations as part of a limited data set file made available to qualified requestors.

Finally, we proposed to extend the use of enrollee-level EDGE data and reports extracted from issuers' EDGE servers (including data reports and ad hoc querying tool reports) to calibrate and operationalize our individual and small group (including merged) market programs (for example, the HHS-operated risk adjustment program, the AV calculator and methodology, and the out-of-pocket calculator), as well as to conduct policy analysis for the individual and small group (including merged) markets (for example, to assess the market impacts of policy options being deliberated). We explained that we believe these additional uses of the enrollee-level EDGE data would enhance our ability to develop and set policy for the individual and small group (including merged) markets and avoid burdensome data collections from issuers.

To further our commitment to increasing transparency in health care markets and help the public better understand these markets, we are finalizing our proposal with one modification. Under our final policy, we will create and make available, on an annual basis, enrollee-level EDGE data as a limited data set file for qualified requestors who seek these data for research purposes. We will not make this limited data set available to requestors for public health or health care operations activities. While these purposes are permitted by the HIPAA Privacy Rule, in light of comments received and HHS' operational limitations, HHS will not make this limited data set file available to requestors for public health or health care operations activities at this time. We note that we may consider exploring the use of the public health and health care operations pathways for making the limited data set file available in the future. We did not propose to extract state and rating area information from issuers' EDGE servers or collect additional data elements, and based on comments received, at this time, we do not believe the benefits from additional data element extractions or collections would outweigh the costs of potential increased risk to issuers' proprietary information and increased issuer

burden. As noted in the proposed rule, we will include the grouped claims identifier beginning with the 2017 benefit year enrollee-level EDGE limited data set file, as that is the first year that data element is available. We are finalizing our proposal to allow HHS to use the enrollee-level EDGE data and reports extracted from issuers' EDGE servers (including data reports and ad hoc querying tool reports) to calibrate and operationalize our individual and small group (including merged) market programs, including to conduct recalibration of the HHS risk adjustment program and to make updates to the AV Calculator, and to conduct policy analysis for the individual and small group (including merged) markets. We believe these additional uses of the enrollee-level EDGE data and reports will enhance our ability to develop and set policy for the individual and small group (including merged) markets and avoid burdensome data collections from issuers. We clarify that our policies regarding HHS uses of the enrollee-level EDGE data apply to the HHS components that currently receive and use such data for purposes of the HHS risk adjustment program. As we stated in the proposed rule, other HHS components will be able to request the EDGE limited data set file for research purposes, as that term is defined under § 164.501. We also note that the enrollee-level EDGE data may be subject to disclosure as otherwise required by law.⁶¹

Comment: Many commenters supported HHS' proposal to create and make available by request a limited data set file using enrollee-level EDGE data. These commenters noted that the limited data set file will support research, public health, external accountability, and transparency. One commenter stated these data will provide researchers with a better understanding of Exchange functions and enrollees' health needs. Another commenter noted these data will help support state departments of insurance in the rate review process. However, numerous other commenters did not support the proposal to offer a limited data set file. Most of these commenters expressed concerns about the potential for unauthorized disclosure of PII and issuer proprietary information. One commenter stated it was particularly concerned with the enrollee-level EDGE data being used for the purpose of health care operations. One commenter stated HHS has not provided adequate assurances that the information would not be used for unauthorized purposes.

⁶⁰ As noted previously, we began extracting a hashed claim identifier to identify all the service line items that belong to the same claim beginning with the 2017 benefit year enrollee-level EDGE extract.

⁶¹ See, for example, 2 U.S.C. 601(d).

Several commenters expressed concerns about the potential of these data to undermine provider contracting and rate negotiations. Some commenters noted that offering these data could erode issuer confidence and could be used by some issuers to competitively price products and game the federal risk adjustment program.

Response: We appreciate the comments we received on our proposal to create and make available by request a limited data set file using the enrollee-level EDGE data. We continue to believe the enrollee-level EDGE data can increase cost transparency for consumers and stakeholders for the individual and small group (including merged) markets and can be a useful resource for government entities and independent researchers to better understand these markets. These benefits align with HHS' goal to promote increased transparency in health insurance markets. We also recognize that any access to and use of the enrollee-level EDGE data should continue to safeguard enrollee privacy and security and issuers' proprietary information. While we acknowledge and appreciate commenters' concerns, we believe the benefits of making these data available for research purposes outweigh the potential risks associated with unauthorized disclosure of these data. While some commenters stated that the limited data set file will benefit public health, others expressed concern. Moreover, HHS does not currently make limited data sets available for health care operations or public health purposes. Therefore, as discussed above, in light of comments received and HHS' operational limitations, HHS will not make this limited data set file available to requestors for public health or health care operations activities at this time. We note that we intend to use the existing process to make limited data set files available and requestors will be required to provide a research purpose as part of their requests.⁶² We believe the potential risks will be mitigated through the existing controls that limit access to these data to qualified requestors who seek these data for research purposes, by requiring requestors to enter into a data use agreement, and by continuing to apply the precautions already in place to mask enrollee identifiers. Under § 153.720, issuers do not upload PII to their EDGE servers, and must establish and use a unique masked identification number for each enrollee and may not include

the enrollee's PII in the masked enrollee identification number. Furthermore, when HHS extracts enrollee-level EDGE data, we create a hashed enrollee identifier, a system-generated random number, that cannot be linked back to the issuers' EDGE servers to identify the issuer or plan. As we noted in the proposed rule and reiterated above, this limited data set file will not include the direct identifiers of the individual or of relatives, employers, or household members of the individual, which are required to be removed under the limited data set definition at § 164.514(e)(2), as issuers do not upload these identifiers to their EDGE servers. Thus, we believe we will continue to protect enrollees' PII and issuers' proprietary information. Furthermore, the limited data set regulations under § 164.514(e) impose specific limitations on use and disclosure of these types of data, and qualified requestors will be required to abide by these requirements and our policies for limited data sets. Requestors will be required to provide a research purpose as part of their request. The data use agreement will require the requestors to maintain, use, and disclose the limited data set only as permitted under § 164.514(e) and report any inappropriate uses or disclosures of these data.⁶³ As discussed below, we are not finalizing a policy to extract state and rating area information from issuers' EDGE servers, and therefore, we will not include those data in the limited data set file developed using enrollee-level EDGE data. Because the limited data set files will not include issuer or plan identifiable information, requestors with access to the limited data set files will not receive or be able to misuse any issuer trade secret information. Additionally, the extracted enrollee-level EDGE data does not include premium information from issuers' EDGE servers and therefore requestors will not be able to determine issuer-specific rate negotiation information. Furthermore, issuers do not upload provider (for example, hospital or physician) identifying information to their EDGE servers. Therefore, these types of provider identifiers cannot be extracted for the enrollee-level EDGE data collection either, mitigating commenters' concerns that the data could reveal issuer-specific provider contracting or negotiated price information. Therefore, we do not believe the enrollee-level EDGE data

could be used to identify issuer-specific proprietary pricing data.

Comment: One commenter sought clarity on the types of entities that can request the limited data set file and the process HHS will use to consider requests. Another commenter noted HHS should develop strict standards for release of these data as a limited data set for which it should seek public comment.

Response: As described in this rule, the limited data set will be made available in accordance with the regulations at § 164.514(e) and existing policies and procedures for limited data set requests. The limited data set file, when available, would be provided to qualified requestors who seek these data for research purposes, consistent with other limited data sets made available by CMS.⁶⁴ Requestors will need to submit a research purpose statement and sign a data use agreement to ensure these data will be used for the stated purpose only and that these data will be maintained, used, and disclosed only as permitted by the agreement or otherwise required by law. We will have final discretion over the decision whether to approve a request for access to the limited data set file.

Comment: Several commenters expressed concern with any use of state and rating area information to support the operation of the risk adjustment program and other HHS programs. Some commenters noted outside entities could identify issuers and, possibly, individual enrollees in a limited data set if it included state and rating area data elements, which could risk issuers' proprietary information and enrollees' PII. However, some commenters who supported release of a limited data set also supported including state and rating area information in the limited data set, stating that this information would make these data more useful to researchers. Most commenters did not support the use of state and rating area information to calibrate the AV Calculator. Most commenters noted this would add increased complexity with little benefit, cause consumer and issuer confusion, and result in unintended consequences affecting the underlying AV Calculator and methodology. One commenter stated that there may not be adequate data in some states and rating areas to build models for the AV Calculator and methodology.

Response: We appreciate the comments we received regarding

⁶² https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html.

⁶³ https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html.

⁶⁴ For information on the CMS limited data set process and data use agreements, see https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_NewLDS.html#Policies.

extraction and use of state and rating area information from issuers' EDGE servers. While we believe state and rating area information would enhance the usefulness of the enrollee-level EDGE data, including for the limited data set file, we agree that the risk of potential unauthorized disclosure of issuer- or plan-level information through inclusion of geographic identifiers outweighs these benefits. We understand that including geographic identifiers in the limited data set would enable qualified requestors who receive the limited data set file to identify issuers in states or rating areas with only one issuer. We appreciate the comments describing concerns regarding the extraction of state and rating area data elements, and as we did not propose to extract and use those data elements for the enrollee-level EDGE data, we are not making any changes in that regard at this time.

We agree with commenters that using geographic information for the AV Calculator and methodology is neither required nor would enhance the current methodology. For AV Calculator and methodology updates in future years, we will continue to use enrollee-level EDGE data in its current format (without the state or rating area information).

Comment: Many commenters did not support the collection of additional data elements, such as enrollees' income level, provider identifier, plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type (deductible, coinsurance, and copayment), that issuers are not already submitting to their EDGE servers. Commenters stated the submission of additional data elements would be administratively complex, burdensome, and beyond the minimum necessary data elements needed for recalibration of the risk adjustment program. One commenter noted HHS should expand the data elements available in the limited data set file, but did not provide further specificity, including how HHS would do that without first collecting those data elements on the issuers' EDGE servers.

Response: We believe that collection of additional data elements that are not currently submitted by issuers to their EDGE servers, such as enrollees' plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type (deductible, coinsurance, and copayment), would enhance the usefulness of the enrollee-level EDGE data, including for the limited data set. However, we acknowledge the commenters' concerns that collection of additional data elements on issuers' EDGE servers could be administratively

complex and burdensome for issuers, as it would increase their data collection requirement, and for HHS, as these data elements would have to be validated and added to the file structure that is submitted through the distributed data environment. We recognize the need to balance the benefits of enhanced transparency and helping the public better understand these markets against minimizing issuer and government costs and burden. As we did not propose to make any changes in this regard, we are not making any such changes at this time, and will consider whether to propose collection of any additional data elements for the EDGE server submissions for future benefit years.

Comment: Some commenters supported HHS broadening its uses of enrollee-level EDGE data to improve and administer programs within HHS' scope, including to recalibrate the risk adjustment program and the AV Calculator and methodology. Most who commented supported HHS broadening the use of the enrollee-level EDGE data as proposed. One commenter noted HHS should not use these data for any other purpose without express issuer permission. Some commenters noted HHS should not use EDGE server data outside of the risk adjustment program, stating that such use would be inconsistent with the intent of using a distributed data environment for administering the risk adjustment program. One commenter did not support the use of EDGE data for policy analysis outside of the risk adjustment program, and recommended that, if HHS proceeds with this proposal, it should define policy analysis and seek public comment.

Response: We are finalizing our proposal to allow HHS to use the enrollee-level EDGE data and reports extracted from issuers' EDGE servers (including data reports and ad hoc querying tool reports) to calibrate and operationalize our individual and small group (including merged) market programs (for example, the HHS-operated risk adjustment program, the AV Calculator and methodology and the out-of-pocket calculator), as well as to conduct policy analysis for the individual and small group (including merged) markets. We agree with commenters that our use of the enrollee-level EDGE data for these purposes will help improve our understanding of the nuances unique to the individual and small group (including merged) markets so that we can be responsive to market fluctuations and pursue updates to these programs, as appropriate. Additionally, we anticipate that leveraging these data in this way will increase efficiencies by

reducing our need to initiate new, potentially burdensome data collections.

HHS may use the enrollee-level EDGE data to help inform which of various policies related to the individual and small group (including merged) markets will further HHS' goals to promote transparency, support innovation in the private sector, reduce burden on stakeholders, and improve program integrity. Generally, policies that could be informed by these data would be developed or revised through the notice-and-comment rulemaking process. We do not believe using the enrollee-level EDGE data and reports extracted from issuers' EDGE servers for the purposes we have outlined is inconsistent with the intent of using a distributed data environment for the HHS operated risk adjustment program. In the 2014 payment notice, we finalized the distributed data model for data collection for the risk adjustment and reinsurance programs when HHS operates those programs on behalf of a State.⁶⁵ In evaluating data collection options, we determined the distributed data collection model proved the most effective approach for obtaining and processing the data necessary for both reinsurance and risk adjustment calculations because such a model would minimize issuer burden while protecting enrollees' privacy. We did not propose and are not making any changes to the risk adjustment data transfer process between issuers and HHS. As discussed previously, we recognize the sensitivity of enrollee-level EDGE data and are taking precautions to safeguard these data. We believe the analyses and uses described in this rule would benefit issuers and the broader individual and small group market (including merged market) stakeholders. While we do not believe issuer permission is necessary for HHS to use enrollee-level EDGE data or reports as HHS would not make issuer proprietary information public nor would HHS require issuers to submit additional data elements, we appreciate the sensitivities related to enrollee-level EDGE data and intend to continue following the current process, under which we engage in notice-and-comment rulemaking prior to expanding uses or disclosures of this data.

d. Risk Adjustment Default Charge (\$ 153.740(b))

As described below, we are finalizing a change to the timeline for publication of the 2017 benefit year risk adjustment data validation results and the

⁶⁵ 2014 Payment Notice, 78 FR 15497.

accompanying collection and payment of adjustments related to these results. Consistent with those changes, the 2018 benefit year summary risk adjustment transfer report issued by June 30, 2019, will not reflect the impact of the 2017 benefit year risk adjustment data validation adjustments on 2018 risk adjustment transfers, but will continue to include information on the assessment and allocation of the applicable benefit year's risk adjustment default charges under § 153.740(b). HHS' calculation of the 2018 benefit year PMPM risk adjustment default charge will be equal to the 90th percentile of the 2018 risk adjustment transfers not adjusted with the results of 2017 risk adjustment data validation.⁶⁶

e. Risk Adjustment User Fee for 2020 Benefit Year (§ 153.610(f))

As noted in this rule, if a state is not approved to operate, or chooses to forgo operating its own risk adjustment program, HHS will operate a risk adjustment program on its behalf. For the 2020 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice,⁶⁷ HHS' 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 PMPM risk adjustment user fee rate 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, merged, and small group markets.

In the 2019 Payment Notice,⁶⁸ we calculated the federal administrative expenses of operating the risk adjustment program for the 2019 benefit year to result in a risk adjustment user fee rate of \$1.80 per billable member per year or \$0.15 PMPM, based on our estimated contract costs for risk adjustment operations, estimates of billable member months for individuals enrolled in risk adjustment covered plans, and eligible administrative and personnel costs related to the administration of the HHS-operated risk adjustment program. For the 2020 benefit year, we proposed to generally use the same methodology to estimate our administrative expenses to operate the program, with the modifications described in this rule. These costs cover development of the risk adjustment models and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment activities related to the HHS-operated program. To calculate the user fee, we divided HHS' projected total costs for administering the risk adjustment program by the expected number of billable member months in risk adjustment covered plans in the 50 states and the District of Columbia where HHS will operate risk adjustment for the 2020 benefit year.

We estimated the total cost for HHS to operate the risk adjustment program for the 2020 benefit year to be approximately \$50 million, and the risk adjustment user fee would be \$2.16 per billable member per year, or \$0.18 PMPM. The updated cost estimates attribute all costs related to the EDGE server data collection and data evaluation (quantity and quality evaluations) activities to the risk adjustment program rather than sharing them with the reinsurance program, which is no longer operational.⁶⁹ We collected amounts under the reinsurance program for administrative

expenses related to that program, which partially funded contracts that were used for both the risk adjustment and reinsurance programs. We no longer allocate indirect costs for personnel or administrative costs to the reinsurance program, and are reflecting the full value of those costs as part of risk adjustment operations for the 2020 benefit year. The risk adjustment user fee costs are also estimated to be slightly higher due to increased contract costs based on additional activities for the risk adjustment data validation program development and execution, including updated cost estimates associated with the non-pilot years of the risk adjustment data validation program, including estimates for error rate adjustments, development of the new risk adjustment data validation audit tool, and additional contractor support for risk adjustment data validation discrepancies and appeals. The estimated costs also incorporate the full personnel and administrative costs associated with risk adjustment program development and operations in the risk adjustment user fee for the 2020 benefit year. The personnel and administrative costs included in the calculation of the 2019 benefit year risk adjustment user fee for the 2019 Payment Notice final rule incorporated only a portion of the personnel costs, and excluded indirect costs. The 2020 benefit year risk adjustment user fee includes the full amount for eligible personnel costs, as well as eligible indirect costs. Finally, we estimated individual and small group market billable member months for the 2020 benefit year to remain roughly the same, as observed in the most recent risk adjustment data available for the 2017 benefit year.

We received one comment on the proposed risk adjustment user fee for the 2020 benefit year, which supported our proposal to establish a risk adjustment user fee for the 2020 benefit year of \$2.16 per billable member per year, or \$0.18 PMPM. We are finalizing the risk adjustment user fee rate for the 2020 benefit year as proposed.

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

We conduct risk adjustment data validation under §§ 153.630 and 153.350 in any state where HHS is operating risk adjustment on the state's behalf, which for the 2020 benefit year is all 50 states and the District of Columbia. The purpose of risk adjustment data validation is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and

⁶⁶ As established in the 2015 Payment Notice at 79 FR 13790, a PMPM default charge is equal to the product of the statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective statewide average PMPM premiums for the risk pool. See 79 FR at 13790. While this percentile was subsequently adjusted to the 90th percentile in the 2017 Payment Notice, the PMPM amount is otherwise calculated in the same manner. See 81 FR 12237.

⁶⁷ See 78 FR 15409 at 15416.

⁶⁸ 83 FR 16930 at 16972.

⁶⁹ Although the 2016 benefit year was the final benefit year for the reinsurance program, close-out activities continued in the 2018 fiscal year, including the collection of the second part of the 2016 benefit year contributions for contributing entities that elected the bifurcated schedule, which were due by November 15, 2017, and are expected to continue in the 2019 fiscal year.

proper functioning of the HHS-operated 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 auditor. 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. Each issuer's initial validation audit is followed by a second validation audit, which is conducted by an entity HHS retains to verify the accuracy of the findings of the initial validation audit. In the proposed rule, we set forth a number of proposed amendments and clarifications to the HHS risk adjustment data validation program in light of experience and feedback from issuers during the first 2 pilot years of the program.

The following is a summary of the general public comments we received related to risk adjustment data validation requirements when HHS operates risk adjustment. Additional comments related to the error estimation methodology and negative error outliers are discussed later in this rule.

Comment: A few commenters urged HHS to adopt the HEDIS (Healthcare Effectiveness Data and Information Set) audit methodology, which only requires medical record review for supplemental codes that the plan pulls from medical records.

Response: We continue to seek ways to improve the HHS risk adjustment data validation program for both accuracy and user experience, and will continue to examine approaches taken by other organizations when making updates to the risk adjustment data validation process. However, because the intent of risk adjustment data validation is to ensure the integrity of the risk adjustment program by validate all diagnoses for which an issuer received credit in risk adjustment, we believe that risk adjustment data validation should include all diagnoses, and not simply be limited to supplemental diagnoses. Additionally, we note that the HEDIS audit methodology is a two-part process that is customized based on an organization's informational systems, and that we believe that the distributed data environment precludes the need for such customization. As such, we are maintaining our current methodology for risk adjustment data validation.

Comment: A few commenters requested relief for issuers experiencing difficulty with obtaining medical records from providers in connection

with the issuers' risk adjustment data validation. One commenter stated that it was having difficulty accessing medical records that included mental health or substance use disorder diagnoses because state privacy law was more stringent than the relevant federal requirements, and that enrollee consent must be obtained even for summary information. Another commenter requested that HHS create a process to exempt issuers from validating HCCs for which a provider refused to supply a medical record and the issuer demonstrated good faith in trying to obtain such record.

Response: In the 2019 Payment Notice, we finalized § 153.630(b)(6) to provide relief to issuers that are prohibited from obtaining medical records by state privacy laws in response to similar concerns expressed by some issuers. We recognize the difficulties that federal and state privacy laws can pose to issuers of risk adjustment covered plans for purposes of risk adjustment data validation, and our intention is not to penalize issuers that seek to obtain the necessary information from providers. We are continuing to consider possible approaches that permit users to meet the requirements of risk adjustment data validation consistent with all applicable privacy laws. Although we appreciate the comments, the proposed rule did not propose changes to § 153.630(b)(6), and we are not making any changes to that provision as part of this final rule.

a. Varying Initial Validation Audit Sample Size (§ 153.630(b))

In the 2014 Payment Notice, we established the risk adjustment data validation program that HHS uses when operating risk adjustment on behalf of a state. Consistent with § 153.350(a), HHS is required to ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that state. The current enrollee sample size selected for the initial validation audit is 200 enrollees statewide (that is, combining an issuer's individual, small group, and merged market enrollees (as applicable) in risk adjustment covered plans in the state) for each issuer's Health Insurance Oversight System (HIOS) ID, based on sample size precision analyses we conducted using proxy data from the Medicare Advantage program. Those analyses calculated a range of sample sizes to target a 10 percent precision at a 95 percent confidence level. The resulting range of sample sizes were between 100 and 300, and we selected

200 as a midpoint.⁷⁰ In the 2015 Payment Notice, we stated that, after the initial years of risk adjustment data validation, we would evaluate our sampling assumptions using actual enrollee data and consider using larger sample sizes for issuers that are larger or have higher variability in their enrollee risk score error rates, and smaller sample sizes for issuers that are smaller or have lower variability in their enrollee risk score error rates. We also stated that we would use our sampling experience in the initial years of risk adjustment data validation to evaluate using issuer-specific sample sizes.

The current initial validation audit sample size of 200 was selected to achieve an estimated 10 percent precision, assuming a distribution of risk score errors similar to that found in the Medicare Advantage risk adjustment data validation program. However, since the HCC group failure rate approach to error estimation (referred to as the HCC failure rate methodology) was implemented beginning with the 2017 benefit year of risk adjustment data validation, we anticipate that the calculated precision would differ from the estimate we used, which was based on the Medicare Advantage error rate data. Therefore, beginning with the 2019 benefit year of risk adjustment data validation,⁷¹ we proposed to vary the initial validation audit sample size and set forth in detail and sought comment on several different approaches for varying the initial validation audit sample size. One proposed approach would vary the initial validation audit sample size based on issuer characteristics, such as issuer size, prior year HCC failure rates, and sample precision. We also solicited comment on an alternative approach to adjusting sample size that would increase sample sizes based on issuer size alone, and would continue to use the proxy Medicare Advantage risk score error rate data for the accompanying precision analyses. Additionally, we solicited comment on whether the issuers' enrollment should be calculated based on the year that is being adjusted or based on the benefit year in which the HCC failure occurred. In response to a comment we received on the 2019 Payment Notice that larger sample sizes could improve the accuracy of issuers' risk adjustment data validation samples, we solicited comment on whether to permit issuers of any size and HCC failure rate to request a larger sample

⁷⁰ See 79 FR 13743 at 13756.

⁷¹ Activities related to the 2019 benefit year risk adjustment data validation generally begin in the second quarter of CY 2020.

size before the applicable benefit year's initial validation audit commences. Finally, we also explained that under these alternative approaches, HHS would not increase the sample above 200 enrollees when performing the second validation audit pairwise means test because a 200-enrollee sample is sufficient to achieve statistical significance in that test.

After consideration of the comments submitted, we are not finalizing any increase to the initial validation audit sample size at this time. We will continue to consider potential changes to initial validation audit sample sizes for future benefit years of risk adjustment data validation. We may revisit these proposals, and may also consider additional alternatives, following further consultation with stakeholders and further analysis of actual enrollee data and non-pilot year risk adjustment data validation results.

Comment: A number of commenters did not support varying the initial validation audit sample size at all (regardless of the approach to do so), and recommended that HHS maintain the current sample size of 200 enrollees. These commenters stated that increasing the initial validation audit sample size would create undue administrative and financial burdens, as well as disruption to plans and the provider community, without improving the quality of the data validation results. Other commenters generally supported varying the initial validation audit sample size, stating that larger sample sizes would help meet desired precision targets, and lend additional credibility to risk adjustment data validation results.

Response: We continue to believe that larger sample sizes would help achieve the goals of increasing initial validation audit sample precision and ensuring the statistical validity of the sample. However, in light of the comments regarding the potential uncertainty related to using 2017 benefit year risk adjustment data validation results to make such changes, we are not finalizing any changes to the initial validation audit sample size at this time. We are maintaining the current initial validation audit sample size of 200 enrollees for all issuers of risk adjustment covered plans required to participate in the HHS risk adjustment data validation program. We are also sensitive to the concerns about the potential increased burdens for stakeholders and will consider how best to strike the balance between mitigating these burdens and increasing precision as we continue to analyze different approaches for varying sample size.

HHS intends to revisit potential changes to initial validation audit sample sizes for future benefit years following further consultation with stakeholders and further analysis of actual enrollee data and non-pilot year risk adjustment data validation results.

Comment: While one commenter supported the proposal to use 2017 benefit year HCC failure rates to develop sample sizes for the 2019 benefit year, another commenter did not support using 2017 risk adjustment data validation results, because the commenter believed that the methodology would not appropriately reflect the 2019 benefit year enrollee population. This commenter noted that any enrollee data used prior to the elimination of the shared responsibility payment would not reflect significant differences that could affect the risk profile and composition of the 2019 benefit year population.

Response: We are not finalizing any changes to the initial validation audit sample size at this time. HHS intends to revisit potential changes to initial validation audit sample sizes for future benefit years following further consultation with stakeholders and further analysis of actual enrollee data and non-pilot year risk adjustment data validation results. We note that 2017 risk adjustment data validation program year results are the most recent results that would be available in the 2019 benefit year, as a result of the operational timing of the risk adjustment data validation program. As such, we note that any approach to modify risk adjustment data validation sampling for an upcoming benefit year based on consideration of HCC failure rates, would rely on previous benefit year failure rates, as more recent data would not be available prior to when initial data validation samples are drawn.

Comment: A few commenters supported the proposal to vary the initial validation audit sample size based on HCC failure rates, sample precision, and issuer size as they believe larger sample sizes would help HHS meet desired precision targets and would lend additional credibility to risk adjustment data validation results. Another commenter encouraged HHS to increase the sample size as a means to potentially reduce data validation error rates. One commenter supported increasing sample size for the initial validation audit for those issuers that fall outside of the confidence interval. Several commenters supported the proposal to vary the initial validation audit sample size based only on issuer size, stating that sample sizes should be

statistically significant and not capped at 200 or 400 for large issuers, and that larger sample sizes would increase the accuracy of the risk adjustment data validation results. Commenters also stated that if issuer size is used as a basis to determine the initial validation audit sample size, HHS should use the issuer's enrollment for the year that is being validated.

However, many other commenters did not support the proposal to vary sample size based on HCC failure rates, sample precision, and issuer size. One commenter stated HHS should only do so once there is sufficient credible experience with the HHS risk adjustment data validation program, citing concerns with making such changes based on 2017 benefit year data validation results, the first non-pilot risk adjustment data validation year under the HHS program. Another commenter did not support this proposal as they stated it effectively disincentives issuers from focusing on reducing their HCC failure rate because any issuer that is an outlier below the confidence interval threshold would be penalized by an increased sample size. The same commenter also noted the potential for annual variation in sample size would make it difficult for issuers to plan for staffing and resource needs.

Other commenters did not support varying the sample size based only on issuer size, expressing concerns over undue administrative burden related to obtaining medical records and substantiating diagnoses, the financial burden of increased administrative costs, and the resulting disruption to plans and the provider community without improving the quality of the data validation results. Yet another commenter stated that until electronic health record interoperability and widespread data sharing is implemented, increasing the sample size would create undue administrative burden.

Response: We share commenters' goals of increasing initial validation audit sample precision and ensuring the statistical validity of the sample, and while we believe that increased sample sizes could help achieve these goals, we are also sensitive to commenters' concerns about the burden of an increase to the sample size and the use of results from the first non-pilot year of risk adjustment data validation to establish larger sample sizes. However, while we recognize these concerns, we do not agree with comments that suggested that increased sample sizes will act as a disincentive for issuers to improve their failure rates. We believe that increasing sample size would

generally increase the sample precision, and could help issuers obtain more favorable risk adjustment data validation results by capturing enrollees with HCCs that may have been missed in smaller samples. We believe that this potential benefit would generally outweigh the additional costs of larger initial validation audit samples. As noted in this rule, we are not finalizing any increase to the initial validation audit sample size at this time, but intend to revisit these proposals and will consider the comments received on these proposals when we revisit potential changes to sample sizes for future benefit years.

Comment: One commenter supported the proposal to use 2017 benefit year HCC failure rates to develop sample sizes for the 2019 benefit year, while another commenter opposed the use of prior-year error rates in determining sample sizes. One commenter stated they believe the current risk adjustment data validation error estimation approach had several flaws that would not be adequately addressed by increasing the risk adjustment data validation sample size for certain issuers. The commenter stated that these flaws included basing adjustments to risk scores solely on risk adjustment data validation outlier status, the use of national benchmarks with large confidence intervals, and adjustment of coefficients by the difference between an outlier issuer's HCC group failure rate and the weighted mean HCC failure rate. The commenter stated that rather than increasing the sample size for certain issuers and building on a flawed process, HHS should reevaluate the risk adjustment data validation methodology in its entirety.

Another commenter opposed allowing issuers to request a larger sample size, stating that allowing such requests could provide opportunities for issuers to intentionally affect the data validation results of other issuers and disproportionately affect HCC failure rates and confidence intervals.

Several commenters suggested alternative approaches to vary the initial validation audit sample size. One commenter suggested adopting sample sizes based on statistical significance with a 90 percent confidence interval and suppression of positive outlier resampling for issuers that have demonstrated a low HCC error rate over multiple years. Another commenter stated HHS should replace the current random sample of 200 enrollees with a data-driven targeted process that identifies situations that warrant investigation. Another commenter recommended HHS evaluate ways to

ensure providers' timely submission of the needed information and documentation to validate the diagnoses captured on the medical record(s). Another commenter did not agree that HHS should continue to use the Medicare Advantage risk score error rate data to determine precision, and recommended that HHS use the available commercial risk adjustment data starting with the 2020 benefit year of risk adjustment data validation. Another commenter stated that if larger sample sizes were adopted, issuers with plans in multiple states should be given the option to use the existing sample sizes for the initial validation audit.

Response: We remain interested in exploring ways to increase sample precision and the statistical validity of the initial validation audit sample and appreciate the different approaches offered. We are sensitive to commenters' concerns about the proposals outlined in the proposed rule and believe that further analysis is needed before making changes to sample sizes. Therefore, at this time, we are not finalizing any increase to the initial validation audit sample size and are maintaining the current sample size of 200 enrollees. We will revisit these proposals, along with the comments submitted, and may consider alternatives following consultation with stakeholders and further analysis of available data. We respond to comments on the risk adjustment data validation error estimation methodology in the preamble below.

b. Initial Validation Audit Sample Size—10th Stratum and Neyman Allocation (§ 153.630(b))

In the initial years of risk adjustment data validation, we constrained the "10th stratum" of the initial validation audit sample—that is, enrollees without HCCs selected for the initial validation audit sample—to be one-third of the sampled initial validation audit enrollees. Under this current approach, the remaining 9 age-risk strata were selected using a Neyman allocation⁷² which optimizes the number of enrollees per stratum for the remaining two-thirds of sampled enrollees. Because we expected enrollees without HCCs to make up the majority of issuers' enrollees, in the absence of data from the individual and small group markets,

we constrained stratum 10 to ensure that healthy enrollees were sampled in the initial years of risk adjustment data validation to establish adequate sampling assumptions.

In the proposed rule, we proposed to extend the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs, such that samples will be assigned to all 10 strata using a Neyman allocation. Since a Neyman allocation approach is expected to provide a more optimal sample size allocation, we explained that we believe using the Neyman allocation for all strata would optimize issuers' initial validation samples and yield better precision than the one-third/two-thirds approach currently used in the enrollee initial validation audit sample. Further, an approach that permits for a larger portion of the sample to be allocated to the HCC strata as compared to the two-thirds allocation used in the current approach would result in a more robust HCC sample in support of the measurement of HCC failure rates under the HCC failure rate methodology finalized in the 2019 Payment Notice.⁷³ Finally, it would increase the probability of achieving our original target of 10 percent precision based on our historical observations of greater error rate variances among the HCC strata. We are finalizing the extension of the Neyman allocation sampling methodology to the 10th stratum, as proposed.

Comment: Some commenters supported extending the Neyman allocation sampling methodology to the 10th stratum, stating that doing so would effectively create an increase in the size of the sample actually available to validate the HCCs submitted to issuer EDGE servers. These commenters noted this approach would permit for a larger portion of the sample to be allocated to the HCC strata as compared to the two-thirds allocation used in the current approach, thereby resulting in a more robust HCC sample in support of the measurement of HCC failure rates under the HCC failure rate methodology finalized in the 2019 Payment Notice. However, other commenters did not support this proposal, as they were concerned that increasing the number of sampled members with HCCs would create undue administrative and financial burden on plans and the provider community without improving the quality of the data validation results or addressing their perceived flaws of the risk adjustment data validation sampling.

⁷² Neyman allocation is a method to allocate samples to strata based on the strata's variances and similar sampling costs in the strata. A Neyman allocation scheme provides the most precision for estimating a population mean given a fixed total sample size. See <http://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n324.xml>.

⁷³ 83 FR 16930 at 16961 (April 17, 2018).

Response: We are finalizing the extension of the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs, such that samples will be assigned to all 10 strata using a Neyman allocation. As noted by some commenters, this is expected to provide a more optimal sample size allocation than the current one-third/two-thirds approach. We believe this will also allow us to achieve greater precision in the HCC error rate methodology by expanding the portion of the sample that may be allocated to the HCC strata (that is, strata 1 through 9) because of the potential for a more robust HCC sample than the current approach provides. We are finalizing the extension of the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs, such that samples will be assigned to all 10 strata using a Neyman allocation. As noted by some commenters, this is expected to provide a more optimal sample size allocation than the current one-third/two-thirds approach. We believe this will also allow us to achieve greater precision in the HCC error rate methodology by expanding the portion of the sample that may be allocated to the HCC strata (that is, strata 1 through 10) because of the potential for a more robust HCC sample than the current approach provides. We further believe that the benefits of more accurate initial validation samples generally outweigh the additional burden of increased sample sizes by capturing enrollees with HCCs that may have been missed in smaller samples. However, as discussed above, we will monitor the impact of this change and continue to consider modifications to the initial validation audit sampling approach for future benefit years in consultation with stakeholders.

c. Second Validation Audit Findings and Error Rate Discrepancy Reporting (§ 153.630(d)(2))

Under § 153.630(d)(2), issuers have 30 calendar days to confirm the findings of the second validation audit or the calculation of the risk score error rate, or file a discrepancy report, in the manner set forth by HHS, to dispute the foregoing. We proposed to amend paragraph (d)(2) to shorten the window to confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate, or file a discrepancy, to within 15 calendar days of the notification by HHS, beginning with the 2018 benefit year risk adjustment data validation. In light of comments received, we will not

shorten the timeframe under § 153.630(d)(2) to 15 calendar days at this time, and will maintain the existing 30-calendar day window for issuers to confirm the findings of the second validation audit (if applicable) or the calculation or the risk score error rate.

We also clarified in the proposed rule that there are two discrepancy reporting windows under § 153.630(d)(2). First, at the conclusion of the second validation audit, we will distribute to issuers their second validation audit findings in the event there is insufficient agreement between the initial and second validation audit results during the pairwise means analysis, and the second validation audit findings will be used for the risk score error rate calculation. The window for issuers who receive second validation audit findings to confirm the findings or file a discrepancy, in a manner set forth by HHS, would begin when the second validation audit findings reports are issued. Second, at the conclusion of the risk score error rate calculation process, we will distribute the risk score error rate calculation results to all issuers for the given benefit year. Once the risk score error rate calculation results are distributed, the window to confirm the results or file a discrepancy, in the manner set forth by HHS, would begin.

We reiterated, consistent with the approach finalized in the 2018 Payment Notice, that issuers are not permitted to appeal the resolution of any discrepancy disputing the initial validation audit sample, or to file a discrepancy or appeal the results of the initial validation audit.⁷⁴ As detailed in the 2015 Payment Notice⁷⁵ and discussed later in this final rule, if sufficient pairwise means agreement is achieved, the initial validation audit findings will be used for purposes of the risk score error rate calculation, and therefore, those issuers will only be permitted to file a discrepancy or appeal the risk score error rate calculation.

Finally, we proposed to amend § 153.630(d)(2) to replace the phrase “audit and error rate” for which an issuer must confirm or file a discrepancy that appears at the end of the provision with “the findings of the second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.” We are finalizing the amendments to § 153.630(d)(2) as proposed, except for the proposed shortening of the applicable timeframe from 15 to 30 calendar days.

⁷⁴ 81 FR 94106.

⁷⁵ See 78 FR at 72334 through 72337 and 79 FR at 13761 through 13768.

The following is a summary of the public comments we received on our proposals regarding the second validation audit findings and risk score error rate discrepancy reporting windows under § 153.630(d)(2).

Comment: Commenters overwhelmingly opposed shortening the discrepancy windows for risk adjustment data validation, with a few suggesting that HHS revisit the idea after a non-pilot year of risk adjustment data validation has occurred. Several commenters suggested we examine other areas of the risk adjustment data validation timeline to possibly make shorter.

Response: In light of comments received, we are not finalizing the proposal to shorten the discrepancy reporting window under § 153.630(d)(2) from 30 to 15 calendar days. Although 15 calendar days is consistent with the initial validation audit sample and EDGE discrepancy submission windows,⁷⁶ we agree that such a change should not be made until after completion of the first non-pilot year of risk adjustment data validation and we have more experience with the process. Additionally, we will continue to examine opportunities to refine the risk adjustment data validation timeline for future benefit years.

d. Default Data Validation Charge

Under § 153.630(b)(10), if an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or submit initial validation audit results, we impose a “default data validation charge,” which the regulation currently refers to in paragraph (b)(10) as a “default risk adjustment charge.” As explained in the 2015 Payment Notice, the default data validation charge is calculated in the same manner as the default risk adjustment charge under § 153.740(b).⁷⁷ With the 2017 benefit year being the first non-pilot year of risk adjustment data validation, and the first year for which HHS may impose the default data validation charge for noncompliance with applicable data validation requirements, we proposed several amendments to further distinguish the default data validation charge assessed under § 153.630(b)(10) from the default risk adjustment charge assessed under § 153.740(b). First, we proposed to amend § 153.630(b)(10) to replace the phrase “HHS will impose a default risk adjustment charge” with “HHS will impose a default data validation charge.” This change is intended to more clearly distinguish

⁷⁶ See §§ 153.630(d)(1) and 153.710(d).

⁷⁷ 79 FR at 13769.

between the two separate risk adjustment-related default charges. Second, we proposed to modify how the default data validation charge under § 153.630(b)(10) would be calculated. While we would generally continue to calculate the default data validation charge in the same manner as the risk adjustment default charge under § 153.740(b), we proposed to calculate the default data validation charge based on the enrollment for the benefit year being audited in risk adjustment data validation, rather than the benefit year during which transfers would be adjusted as a result of risk adjustment data validation. By way of example, if an issuer is subject to the default data validation charge for the 2021 benefit year risk adjustment data validation and it offers risk adjustment covered plans in the same state market risk pool in the 2022 benefit year, its default data validation charge would be calculated based on 2021 benefit year enrollment data (rather than 2022 benefit year enrollment data). Under this example, the default data validation charge this issuer would receive for failing to comply with the 2021 benefit year risk adjustment data validation requirements would equal a per member per month (PMPM) amount for the 2021 benefit year multiplied by the plan's enrollment for the 2021 benefit year as follows:

$$T_n = C_n * E_n$$

Where:

T_n = total default data validation charge for a plan n ;

C_n = the PMPM amount for plan n ; ⁷⁸ and

E_n = the total enrollment (total billable member months) for plan n . ⁷⁹

Third, we proposed to amend the allocation approach for distribution of default data validation charges among

issuers. We proposed to allocate a default data validation charge to the risk adjustment data validation issuers that were part of the same benefit year risk pool(s) as the noncompliant issuer. However, we would not allocate default data validation charges to any other noncompliant issuers in the same benefit year risk pool(s). This approach is consistent with the methodology for allocating the default risk adjustment charges under § 153.740(b), and includes all issuers in the same benefit year risk pool(s) that could be subject to a risk score adjustment as the result of other issuers' risk adjustment data validation results. Issuers in the same benefit year risk pool(s) that are exempt from the risk adjustment data validation requirements would also be included in the allocation of any default data validation charges. Therefore, we proposed to allocate any default data validation charges collected from noncompliant issuers among the compliant and exempt issuers in the same benefit year risk pool(s) in proportion to their respective market shares and risk adjustment transfer amounts for the benefit year being audited for risk adjustment data validation.

As an illustrative example, assume there are 4 issuers (A, B, C, and D) in the individual non-catastrophic risk pool in state X for the 2017 benefit year, and an additional issuer, E, in the 2018 benefit year individual non-catastrophic risk pool in state X. Assume:

- Issuer A does not comply with risk adjustment data validation requirements for the 2017 benefit year and is assessed a default data validation charge.
- Issuer B was exempt from risk adjustment data validation for the 2017 benefit year because it was a small issuer (that is, it had 500 or fewer billable member months statewide in state X).
- Issuers C and D complied with applicable 2017 benefit year risk adjustment data validation requirements.
- Issuer E was not in the individual non-catastrophic risk pool in state X for 2017.

Issuer A's default data validation charge would be allocated to issuers B, C, and D in proportion to their 2017 benefit year transfer amounts and market shares. While Issuer B was not subject to risk adjustment data validation for the 2017 benefit year, it was still part of the same state market risk pool and would be subject to possible risk score adjustments due to the risk adjustment data validation results of Issuers C and D. Since Issuers C and D also participated in the

individual non-catastrophic risk pool in state X for 2017 and complied with applicable data validation requirements, they would also receive part of Issuer A's default data validation charge. However, Issuer E was not part of the individual non-catastrophic risk pool in state X until the 2018 benefit year, and therefore, would not receive any part of Issuer A's 2017 benefit year default data validation charge.

In the proposed rule, we noted that we intend to publish the default data validation charge information in the benefit year's report(s) released under § 153.310(e) in which transfers are adjusted based on risk adjustment data validation results. We also explained that, following release of the report under § 153.310(e), these amounts would then be included as part of the monthly payment and collection processes described in § 156.1215 alongside the collection of risk adjustment charges and payments calculated under the HHS risk adjustment methodology for the applicable benefit year.

Fourth, we clarified that a default data validation charge under § 153.630(b)(10) is separate from risk adjustment transfers for a given benefit year, unlike a default risk adjustment charge under § 153.740(b), which replaces the issuer's transfer amount for that benefit year. For example, if an issuer fails to submit initial validation audit results for the 2017 benefit year, it would receive a default data validation charge based on 2017 benefit year data calculated in accordance with the formula outlined in this final rule. This default data validation charge for the 2017 benefit year would be in addition to, and separate from, the issuer's 2018 benefit year risk adjustment payment or charge amount as calculated under the HHS-operated risk adjustment methodology. This means that an issuer may owe both a risk adjustment charge and a default data validation charge (for example, an issuer could owe a risk adjustment charge for the 2018 benefit year and a default data validation charge for the 2017 benefit year risk adjustment data validation). Similarly, an issuer may owe a default risk adjustment charge for a given benefit year, alongside a default data validation charge for the benefit year being audited (for example, an issuer could owe a default risk adjustment charge for the 2018 benefit year, as well as a default data validation charge for the 2017 benefit year).

We offered these proposals and clarifications about how HHS will assess and allocate the default data validation charge at this time to allow issuers to better understand the

⁷⁸ Except as otherwise provided in this final rule, the default data validation charge is calculated in the same manner as the risk adjustment default charge under § 153.740(b). See 79 FR at 13769. As established in the 2015 Payment Notice, a PMPM default charge is equal to the product of the statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective statewide average PMPM premiums for the risk pool. See 79 FR at 13790. While this percentile was subsequently adjusted to the 90th percentile in the 2017 Payment Notice, the PMPM amount is otherwise calculated in the same manner. See 81 FR at 12237. The 2020 Payment Notice proposed rule did not propose, and this final rule does not make, any changes to this aspect of the calculation of the default data validation charge.

In the 2015 Payment Notice at 79 FR 13790, we provided that E_n could be calculated using an enrollment count provided by the issuer, enrollment data from the issuer's MLR and risk corridors filings for the applicable benefit year, or other reliable data sources. The proposed rule did not propose, and this final rule does not make, any changes to the sources that could be used.

⁷⁹ Ibid.

implications of noncompliance with initial validation audit requirements as risk adjustment data validation operations transition away from the pilot years of the program.

We are finalizing the amendments to § 153.630(b)(10), as well as the proposed changes to the calculation and allocation of the default data validation charge, as proposed. As outlined further below, we are modifying the timing for publication, collection and distribution of the default data validation charges.

Comment: Commenters were in favor of basing the default data validation charge on the enrollment of the year being audited rather than the year being adjusted. One commenter requested that we clarify the allocation methodology for issuers that have exited the market.

Response: We are finalizing the proposals related to the default data validation charge, but are modifying the timing for publication, collection, and distribution of the default data validation charges. Rather than releasing this information as part of the annual summary risk adjustment transfer report released by June 30, information on default data validation charges and allocations will be published as part of the separate announcement of risk adjustment data validation results and related adjustments to risk adjustment transfers for the applicable benefit year so that issuers will not have to consult multiple reports for information on payments and charges related to risk adjustment data validation. Default data validation charge amounts will be included as part of the monthly payment and collection processes described in § 156.1215 alongside the collection and distribution of the risk adjustment data validation-related adjustments to risk adjustment transfers. Please refer to the preamble section below on negative error rate outlier markets for further details on the updated timeline for publication of risk adjustment data validation results, as well as collection and disbursement of risk adjustment data validation related adjustments to risk adjustment transfers.

We clarify that if an issuer is in a state market risk pool with a noncompliant issuer in a given benefit year, and then exits the state market risk pool in the subsequent benefit year, it will still be eligible to receive its portion of the allocation from the noncompliant issuer's default data validation charge. This approach is consistent with the general policy established in the 2019 Payment Notice⁸⁰ to adjust exiting issuers' risk adjustment transfers based on risk adjustment data validation

results, and it allows those who are compliant with applicable risk adjustment data validation related adjustments to gain the benefit of an allocation amount.

e. Second Validation Audit Pairwise Means Test

In the 2014 Payment Notice, we provided that a second validation audit will be conducted by an entity retained by HHS to verify the accuracy of the findings of the initial validation audit.⁸¹ Consistent with § 153.630(c), HHS must select a subsample of the risk adjustment data validated by the initial validation audit for the second validation audit. In the 2015 Payment Notice, we indicated that to select the subsample, the second validation auditor will use a sampling methodology that allows for pairwise means testing to establish a statistical difference between the initial and second validation audit results.⁸² This pairwise means test uses a 95 percent confidence interval (and a standard deviation of 1.96). To do pairwise means testing under the current approach, the second validation auditor tests a subsample of enrollees from an issuer's initial validation audit sample of 200 enrollees. If the pairwise means test results for a subsample indicate that the difference in enrollee results between the initial and second validation audits is not statistically significant, the initial validation audit results are used for calculation of HCC failure rates and risk score error rates. If the pairwise means test results for the subsample yield a statistically significant difference, the second validation auditor performs another validation audit on a larger subsample of enrollees from the initial validation audit. The results from the second validation audit of the larger subsample are again compared to the results of the initial validation audit using the pairwise means test with a subsample size of up to 100 enrollees. If there is no statistically significant difference between the initial and second validation audits of the larger subsample, HHS will apply the initial validation audit error results to calculate the HCC failure rates and risk score error rates. However, if a statistically significant difference is found based on the second validation audit of the larger subsample up to 100 enrollees, HHS will apply the second validation audit results to the larger

subsample to calculate the HCC failure rates and risk score error rates.

Based on the results of the second validation audit for the 2016 risk adjustment data validation pilot year, we proposed to modify the statistical subsampling methodology to further expand the comparison of results between the initial and second validation audits. Specifically, when the larger subsample (of up to 100 enrollees) results indicate a statistically significant difference, we believe that further sampling by the second validation auditor is necessary and appropriate to determine whether the second validation audit results from the full sample should be used in place of the initial validation audit results. Therefore, we proposed that, if a statistically significant difference is found based on the second validation audit of the larger subsample (of up to 100 enrollees), HHS would expand its sample to the full initial validation audit sample to consider whether the second validation audit results of the full sample or the subsample (of up to 100 enrollees) results should be used in place of initial validation audit results. Allowing the further testing of the sample provides assurance and confidence in the second validation audit results and the associated error estimation rate that will ultimately be used to adjust risk scores and transfers.

To determine whether to expand the second validation audit to the full initial validation audit sample, we proposed to use a precision analysis. We proposed to use precision metrics, including the standard error and confidence intervals, to determine if the second validation audit review of the larger subsample (of up to 100 enrollees) is of high or low precision. If the results of the second validation audit precision analysis determined that the precision level is high, we proposed that HHS would use the second validation audit results for the larger subsample (of up to 100 enrollees) in place of the initial validation audit results for the error estimation and calculation of adjustments for plan average risk score, as applicable. However, if the second validation audit precision analysis for a larger subsample (of up to 100 enrollees) determined that the precision level was low, the second validation audit would expand and use the full initial validation audit sample of 200 enrollees for error estimation and calculation of adjustments for plan average risk score.

We are finalizing this approach as proposed.

Comment: One commenter stated that it believed the proposal would not substantially improve the process.

⁸¹ 78 FR 15437.

⁸² 79 FR 13761.

⁸⁰ 83 FR 16965.

Another commenter did not explicitly oppose the proposal, but suggested better pairwise accuracy could be achieved through increased education and outreach.

Response: HHS has an interest in providing issuers every opportunity to use the results submitted by the initial validation audit entity and attested to by the issuer before taking the step of replacing those results with second validation audit findings. Expanding the subsample further and then testing precision when the larger subsample (of up to 100 enrollees) results indicate a statistically significant difference allows additional opportunity to find the initial validation audit findings are valid. We disagree with the commenter that these proposals would not substantially improve the process. On the contrary, we believe that allowing further testing of the sample provides assurance and confidence in the audit results and the

associated error estimation rate that will ultimately be used to adjust risk scores and transfers. Therefore, we are finalizing this approach as proposed. We remain committed to providing training and support as needed to improve the initial validation audit process and subsequent pairwise results.

f. Error Estimation for Prescription Drugs

In the proposed rule, we proposed several options for incorporating RXCs in the risk adjustment data validation processes beginning with the 2018 benefit year risk adjustment data validation. Because the incorporation of payment RXCs into the risk adjustment models for adults began with the 2018 benefit year, we discussed whether modification was appropriate to the error estimation methodology to take into account the RXC failure rates as

part of the HHS risk adjustment data validation process and we proposed various ways to incorporate RXCs into risk adjustment data validation processes, including adding RXCs to the error estimation methodology by treating RXCs similar to HCCs.

The first proposal that we outlined would incorporate RXCs into the HCC failure rate methodology by adding each RXC as a separate factor, similar to an “HCC”, for classification into the low, medium, and high HCC groups determined by the national failure rates for each RXC. To apply this change to the error estimation methodology finalized in the 2019 Payment Notice, we proposed the definition of superscript *h* would expand to a list of codes including both the 128 HCCs and 12 RXCs whereby HHS would first calculate the failure rate for each HCC and RXC in issuers’ samples as:

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

Where:

h_r is the set of codes including 128 HHS HCCs and 12 RXCs.

Freq_EDGE^{h,r} is the frequency of HCC code *h* or RXC code *r* occurring on EDGE, which is the number of sampled enrollees recording HCC code *h* or RXC code *r* on EDGE.

Freq_IVA^{h,r} is the frequency of HCC code *h* or RXC code *r* occurring in initial validation audit results, which is the number of sampled enrollees with HCC code *h* or RXC code *r* in initial validation audit results.

FR^{h,r} is the failure rate of HCC code *h* or RXC code *r*.

HHS would then create three “HCC/RXC” groups based on the HCC failure rates and RXC failure rates derived in

the above calculation. These “HCC/RXC” failure rate groups would rank all HCC failure rates and RXC failure rates to assign each unique HCC and RXC in the initial validation audit samples to a high, medium, or low failure rate group. To assign each HCC and RXC to a “HCC/RXC” failure rate group, we proposed to use the current HCC failure rate ranking methodology that ranks each HCC/RXC failure rate divided into three groupings based on weighted total observations or frequencies of that HCC/RXC across all issuers’ initial validation sample, or assigning HCCs and RXCs failure rates by taking into consideration the ranking of related HCCs and RXCs in the grouping. Under this approach, we would maintain a single

classification for HCC and RXC high, medium, or low groups, instead of creating two separate classifications of RXCs and single component HCCs.

Alternatively, we proposed incorporating RXCs as a separate “HCC” grouping in the error estimation methodology. Under this approach, we would keep the 128 HCCs in the three groups, but combine all RXCs into an additional, fourth separate group. Therefore, separate RXC and HCCs groups would be created, and their failure rates would be computed within those four groupings. This approach to group RXCs would be the same as for HCC groupings, which is based on the failure rates *FR* of the 12 RXCs:

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

Where:

r is the set of 12 RXCs.

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

$Freq_IVA^r$ is the frequency of RXC code r occurring in initial validation audit results, which is the number of sampled enrollees with RXC code r in initial validation audit results.

FR^r is the failure rate of RXC code r .

While we assumed that RXCs may be easier to validate, this proposed approach could take into consideration the potential differing failure rates within the RXC groupings as opposed to the single component HCC groupings, or isolate the RXC failure rates to a separate grouping from HCCs before

applying those failure rates to the error rate calculation. This alternative approach would have also resulted in an additional grouping in the error estimation methodology, and having more groupings means that the number of groupings where it is possible for an issuer to be an outlier would increase. Further, in the event that all RXCs do not have similar, low failure rates, the confidence interval for an RXC-only group could be quite large, resulting in a significant difference between the outliers' failure rates to the group's failure rate mean, and by extension, could result in a larger failure rate adjustment factor for the RXC-only group.

In addition to adopting one of the above approaches to group RXCs as part

of the error estimation methodology, we would also need to incorporate RXCs into the error rate calculation under the error estimation methodology. To do so, we proposed three alternative approaches to incorporate and adjust for RXCs and RXC-HCC interaction factors in the error rate calculation.

One option that we proposed to incorporate the RXCs in the error rate calculation was to add RXCs to the current methodology of calculating error rates, without accounting for any HCC-RXC interaction factors. To incorporate RXCs in the current error rate calculation under this option, we proposed to modify the formula to calculate an enrollee's adjustment $Adjustment_{i,e}$ as follows:

BILLING CODE 4150-28-P

$$Adjustment_{i,e} = \frac{\sum_c (RS_{i,e}^{c,G} * Adjustment_i^G)}{\sum_c (RS_{i,e}^{c,G})}$$

Where:

$RS_{i,e}^{c,G}$ is the risk score component of a single HCC or RXC code c (belonging to

HCC/RXC group G) recorded on EDGE for Enrollee e of Issuer i .

This approach would be the simplest approach to adjusting RXCs in the error rate calculation, as $RS_{i,e}^{c,G}$ generally retains the same definition as in the 2019 Payment Notice⁸³ for $RS_{i,e}^{hcc,G}$ and the resulting calculation would be completed as follows:

$$RS_{i,e}^{c,G} = RS_{i,e}^{c_hcc/rxc,G}$$

Where:

$RS_{i,e}^{c_hcc/rxc,G}$ is the risk score component of a code c as a single HCC or RXC, without considering the interaction coefficients between code c and other codes for Enrollee e of Issuer i . However, this approach would mean that the interaction of the risk score coefficients between the single component HCC and the RXC would not be considered in the error rate calculation, which may be an oversimplification of this calculation.

As a second alternative, we solicited comments on the adjustment of the RXCs in the error rate calculation as part of the risk score coefficient for a single component HCC by adjusting the risk score coefficient of the RXC-HCC interaction factor, if the coefficient exists. This step would start with the coefficient for a single component HCC and RXC and then adjust both single component coefficients with the full interaction term for both the HCC and RXC to calculate the error rate. Under this approach, if there is no coefficient, the single component HCC and RXC would not be adjusted by an interaction term. Under this approach, $RS_{i,e}^{c,G}$ would be defined as:

$$RS_{i,e}^{c,G} = RS_{i,e}^{c_hcc/rxc,G} + RS_{i,e}^{c_x_hxr,G}$$

⁸³ 83 FR 16930 at 16963.

Where:

$RS_{i,e}^{c_hcc/rxc,G}$ is the risk score component of a code c as a single HCC or RXC, without

considering the interaction coefficients between code c and other codes for Enrollee e of Issuer i .

$RS_{i,e}^{c_x_hXr,G}$ is the risk coefficient for the interaction between an HCC and an RXC, with

the interaction term existing between code c and another code x for Enrollee e of Issuer i .

G is the HCC/RXC group for code c .

BILLING CODE 4150-28-C

The purpose of this second alternative for incorporating RXCs in the error rate calculation was to capture the sampled enrollee's characteristics and interaction between the single component HCC and RXC that may provide a more accurate calculation than not accounting for any interaction between the single component HCC and RXC. However, this approach would have added an additional step to the error rate calculation, whereby the risk score coefficient for a condition would be adjusted by the interaction coefficients between the single component HCC and the RXC and would have taken into account the full interaction coefficient separately for the HCC and RXC, which may result in an over-adjustment for the interaction terms.

A third alternative to incorporating RXCs as part of the error rate calculation would be to adjust the risk score coefficient for a single component HCC and RXC by a modified interaction coefficient between the single component HCC and RXC indicator, if the coefficient exists. If there is no coefficient, the single component HCC and the RXC would not be adjusted by an interaction coefficient. This alternative approach was intended to capture a sampled enrollee's specific characteristics and interaction between HCC and RXC and modify the interaction such that the total adjustments are equal to the total interaction term value.

We also generally solicited comment on how to weight risk score coefficients and account for the interaction terms between the single component HCC and the RXCs in calculating the error rate under these alternative proposed approaches. Additionally, in the error estimation methodology finalized in the 2019 Payment Notice, we did not include the severity illness indicator interactions for HCCs as they can be triggered by multiple combinations of

HCCs, which would be overly complex to implement. As part of our current evaluation of the impact of adjusting for the RXC–HCC interactions in the error estimation methodology, we also sought comment on whether we should similarly not adjust for the RXC–HCC interactions.

We solicited comment on all of these proposed approaches for incorporating RXCs into the error estimation methodology and error rate calculation, including whether we should consider alternative options.

Finally, as an alternative to the aforementioned proposed policies, we stated that we were also considering methods for incorporating RXCs (or all drugs) into the risk adjustment data validation process other than as part of the error estimation methodology and error rate calculation. We proposed an option to treat RXC errors as a data submission issue. Specifically, under this approach, we would incorporate RXCs or all drugs into risk adjustment data validation as a method of discovering materially incorrect EDGE server data submissions in the same or similar manner to how we address demographic and enrollment errors discovered during risk adjustment data validation.⁸⁴ Under this approach, instead of incorporating RXCs into the error estimation methodology and error rate calculation, we would treat RXC or general drug errors discovered during risk adjustment data validation in a manner similar to an EDGE data discrepancy, which is addressed in the current benefit year under § 153.710(d). As such, these RXC or general drug errors would be the basis for an adjustment to the applicable benefit year risk score and original transfer amount, rather than the subsequent benefit year risk score. Any material errors identified through this process would result in a decrease to the issuer's

original risk score, thereby resulting in a reduced risk adjustment payment or an increased risk adjustment charge for that issuer. If this alternative approach were adopted, the identification of RXC or general drug errors could also have the effect of reducing charges or increasing payments to other issuers in the state market risk pool, holding constant the other elements of the state payment transfer formula, due to the budget neutral framework for the HHS operated program. We solicited comment on this alternative approach, especially in comparison to the proposals for incorporating RXCs into the error estimation methodology or error rate calculation, and on whether other specific requirements would be needed to verify materiality of risk score impacts if we were to treat RXC or general drug errors discovered during risk adjustment data validation as a data submission issue through the EDGE data discrepancy process under § 153.710(d).

After consideration of the comments received, we are finalizing an approach under which we will incorporate RXCs into risk adjustment data validation as a method of discovering materially incorrect EDGE server data submissions in a manner similar to how we address demographic and enrollment errors discovered during risk adjustment data validation, and will pilot the incorporation of these drugs into the risk adjustment data validation process for the 2018 benefit year. As a pilot year, the identification of RXC errors during the 2018 benefit year risk adjustment data validation process will not be used to adjust 2018 risk scores or transfers.

Comment: While some commenters generally supported adding RXCs to the error estimation methodology, many commenters discouraged HHS from doing so because they did not generally believe that adding this complexity to the error estimation methodology would deliver improved risk adjustment data validation results, and expressed

⁸⁴ See 83 FR 16930 at 16970 through 16971.

concern that it instead would increase administrative and financial burden for issuers and the provider community. Some commenters were concerned about making changes to the error estimation methodology when issuers have not yet seen the first non-pilot year of risk adjustment data validation results. Some commenters recommended retaining the current error estimation methodology that focuses on validating HCCs and not expanding the error rate methodology to include RXCs, while one commenter noted the proposed rule did not address changes that would be made to the member-level risk score adjustment calculation. Some commenters recommended that further consideration be given to the value of including RXC related errors before incorporating RXCs (or all drugs) as part of the data validation process. However, several other commenters supported treating RXCs in a manner similar to how we address demographic and enrollment errors discovered during the data validation process (or an EDGE server data discrepancy) as a more efficient and less complicated process than the other options.

Response: As discussed in the proposed rule, we recognize there may be differences between HCCs and RXCs that need to be considered when incorporating RXCs into risk adjustment data validation. For example, it may be more straightforward for initial validation auditors to validate an RXC rather than an HCC because HCC validation requires recoding a medical record, with a potential for greater variation. However, given the incorporation of RXCs into the HHS risk adjustment adult models beginning with the 2018 benefit year and their ability to affect an issuer's risk score and calculated transfers in the state market risk pool, we believe it is important that RXCs are validated in some manner as part of risk adjustment data validation. Therefore, based on comments received, we are finalizing an approach, starting with 2018 benefit year risk adjustment data validation, under which we will incorporate RXCs into risk adjustment data validation in a manner similar to how we address demographic and enrollment errors discovered during the data validation process. This approach will not affect or require changes to the error estimation methodology, including calculation of the individual member error rate, which was finalized in the 2019 Payment Notice.⁸⁵ That is, RXC failures will not be measured as part of the HCC failure rates used to adjust

enrollees' risk scores, but will be treated as an EDGE discrepancy. This approach will ensure that RXCs are being validated while limiting burden to issuers and providers to validate these RXCs. Furthermore, for consistency with the EDGE server data discrepancy process and the policy regarding adjustments to transfers due to submission of incorrect data⁸⁶, we are finalizing that RXC errors will only result in a reduced risk adjustment payment or an increased risk adjustment charge for that discrepant issuer with the errors and will not result in increased payment or decreased charges for that issuer.

Additionally, in response to comments, we are finalizing a policy to treat the incorporation of RXCs into 2018 benefit year risk adjustment data validation as a pilot year to allow HHS and issuers to gain experience in validating RXCs before RXCs are used to adjust issuers' risk scores. This approach will also allow for HHS and issuers to primarily focus efforts and resources on validating HCCs in the 2018 benefit year risk adjustment data validation and understanding the first year of risk adjustment data validation results, which issuers will receive later this year (reflecting 2017 benefit year data validation results).

Comment: Several commenters suggested piloting the incorporation of RXCs into the risk adjustment data validation process to gain experience in how best to evaluate RXC errors and understand potential implications in the risk adjustment data validation process. Some of these commenters recommended a pilot for 2 years to allow HHS, issuers and other stakeholders to gain experience with the incorporation of RXCs into the risk adjustment data validation process. Other commenters requested that HHS postpone the implementation of RXCs in risk adjustment data validation or focus current data validation efforts on HCCs. One of these commenters noted that HHS would have the means to address any obvious fraudulent activity regarding RXCs discovered as part of a pilot process.

Response: We are finalizing the incorporation of RXCs in risk adjustment data validation beginning with the 2018 benefit year. However, in response to comments, we will treat the 2018 benefit year as a pilot year for purposes of incorporating RXCs, similar to the pilot years that we allowed for

other aspects of risk adjustment data validation for the 2015 and 2016 benefit years. Under this approach, the risk adjustment data validation processes will proceed for the 2018 benefit year in a similar manner as the 2017 benefit year, with the addition of RXCs being included and treated in a manner similar to how we treat demographic and enrollment errors during data validation. However, the identification of RXC errors as part of 2018 risk adjustment data validation will not be used to adjust risk scores. While we do not agree with commenters that piloting RXCs in risk adjustment data validation for 2 years is necessary at this time, we agree with commenters who suggested that piloting the incorporation of RXCs in risk adjustment data validation for the 2018 benefit year will provide HHS, issuers, and stakeholders with experience in validating RXCs and understanding potential implications before using identified RXC errors to adjust risk scores. Our intention at this time is to fully implement the incorporation of RXCs into risk adjustment data validation, as outlined in this final rule, beginning with the 2019 benefit year of risk adjustment data validation.

Comment: Commenters wanted additional information on how HHS plans to validate RXCs, with one commenter recommending a verification approach where the audit would confirm that the prescription is a valid paid claim by reviewing this information on issuers' source systems (similar to how demographic and enrollment data is validated in risk adjustment data validation), and not obtain the actual prescription, which a commenter thought would be burdensome and would lead to false results. Some commenters sought clarification as to what constitutes a valid prescription that would need to be obtained to validate the RXC and what would be considered acceptable documentation within the medical record system for the purposes of validating the RXC. One commenter, who wanted clarification on how HHS determines the materiality of errors and the size of the adjustment for data discrepancies, noted that issuers may not have the ability to provide other types of documentation to validate that a prescription was written by a provider, and another commenter stated that as long as the issuer paid for the drug, it would be difficult to see how the issuer acted in bad faith and that applying a data validation process that makes sure the issuer's claims and payments match what is reported to

⁸⁶ See the November 15, 2018, *Evaluation of EDGE Data Submissions for the 2018 Benefit Year Guidance*, available at <https://www.cms.gov/CCHIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2018.pdf>. Also see 83 FR at 16970–16971.

⁸⁵ 83 FR 16930 at 16961–16966.

EDGE is the only validation that might identify potential inappropriate or fraudulent actions. Other commenters suggested varying types of collaboration with stakeholders on methodology and documentation standards related to incorporation of RXCs into risk adjustment data validation.

Response: As discussed in the 2018 Payment Notice,⁸⁷ HHS does not perform risk adjustment data validation audits with the intent of determining whether a clinician correctly diagnosed a patient. Rather, HHS focuses on ensuring 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 paid by the issuer, and whether the RXC eligible service code on a medical claim was paid by the issuer.

We believe that this type of approach to RXCs will be an effective approach for validating that issuers are providing accurate RXC claims information while limiting the burden on issuers and other stakeholders involved in the risk adjustment data validation process. Specifically, to validate RXCs in risk adjustment data validation, we will conduct a claims-based validation to evaluate the accuracy of RXC data submissions. Under this approach, similar to how we confirm demographic and enrollment data during the risk adjustment data validation process, we will not require the issuer to obtain a valid prescription for the RXC and will only subject issuers' source system documentation of pharmacy claims or medical claims to the initial validation auditor and second validation auditor review, thereby limiting the burden on issuers to validate the RXCs.⁸⁸

Consistent with the treatment of demographic and enrollment errors discovered during data validation,⁸⁹ we intend to communicate with issuers where significant RXC errors are found.

Furthermore, in a non-pilot year, we would only adjust issuer risk scores for RXC errors in cases where an issuer has materially incorrect EDGE server RXC data submissions, and these discovered RXC errors would be the basis for an adjustment to the applicable benefit year transfer amount for the state market risk pools in question. We will work with these issuers to resolve potential

discrepancies in a manner similar to the EDGE data submission discrepancy process.⁹⁰ We also intend to be in communication with all issuers in affected state market risk pools throughout the second validation audit process when RXC errors or other identified data validation errors could result in adjustments to risk adjustment transfers.

This approach will target materially incorrect RXC data and will not target an isolated RXC data error, which is similar to the goal of the error estimation methodology for HCCs finalized in the 2019 Payment Notice—to avoid adjusting all issuers' risk adjustment transfers for expected variation. The approach is also similar to how demographic and enrollment validation is occurring where the review involves the identification of errors that could result in the initiation of a discrepancy process for adjustments.⁹¹ Additionally, we intend to learn from the experience of validating RXCs during the pilot year to inform and potentially refine the approach for incorporating review of RXCs in data validation in future benefit years. However, as noted above, our intention at this time is to fully implement the incorporation of RXCs into risk adjustment data validation, as outlined in this final rule, beginning with the 2019 benefit year of risk adjustment data validation.

g. Risk Adjustment Data Validation Adjustments in Exiting and Single Issuer Markets and Negative Error Rate Outlier Markets

i. Risk Adjustment Data Validation Adjustments in Exiting Issuer Markets

Under the risk adjustment data validation program, adjustments to transfers are generally made in the benefit year following the benefit year that was audited. For issuers that exit the market following the benefit year being audited, and therefore do not have transfers to adjust during the following benefit year, we previously finalized an exception to this general rule such that we will adjust the exiting issuer's prior year risk scores and associated transfers where it has been identified as an outlier through the HCC failure rate methodology during risk adjustment data validation.⁹² In the proposed rule,

we proposed to amend our policy to provide that, if an exiting issuer is found to be a negative error rate outlier, HHS would not make adjustments to that issuer's risk score and its associated risk adjustment transfers as a result of this negative error rate outlier finding. A negative error rate will have the effect of increasing an issuer's risk score and thereby increasing its calculated risk adjustment payment or reducing its calculated risk adjustment charge. To avoid retroactively re-opening a risk pool to make adjustments to other issuers' transfers based on an exiting issuer's negative error rate, we proposed to re-open the issuer's risk score and its associated risk adjustment transfers in a prior benefit year only if the exiting issuer was found to have had a positive error rate, and was therefore overpaid or undercharged based on its risk adjustment data validation results. When the exiting issuer is a positive error rate outlier, HHS would collect funds (either increasing the charge amount or reducing the payment amount) from the exiting issuer and redistribute the amounts to other issuers who participated in the same state market risk pool in the prior benefit year. This approach was intended to help ensure that issuers are made whole even if an issuer with a positive error rate exits the state, without the additional burdens associated with having transfers adjusted (including the potential for additional charges being assessed) for a prior benefit year for a negative error rate outlier when an issuer decides to exit a state.

Further, we proposed that to be considered an exiting issuer under this policy, the issuer would have to exit all of the markets and risk pools in the state (that is, not selling or offering any new plans in the state). If an issuer only exits some markets or risk pools in the state, but continues to sell or offer new plans in others, it would not be considered an exiting issuer under this policy. Finally, we clarified that under this proposed policy, a small group market issuer with off-calendar year coverage who exits the market but has only carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold) would be considered an exiting issuer and would also be exempt from risk adjustment data validation for the benefit year with the carry-over coverage. Individual market issuers offering or selling any new individual market coverage in the subsequent benefit year would be subject to risk adjustment data

⁹⁰ See, <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2018.pdf>; <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RA-Adjustment-Guidance-9-2-15.pdf> and [https://www.regap.info/uploads/library/DDC_AttestDisc_Slides_050818_v2_5CR_050818\(1\).pdf](https://www.regap.info/uploads/library/DDC_AttestDisc_Slides_050818_v2_5CR_050818(1).pdf).

⁹¹ 83 FR at 16970.

⁹² 83 FR 16965.

⁸⁷ 81 FR 94077.

⁸⁸ Further details on the process for how RXCs will be validated during the pilot year will be provided in the 2018 Risk Adjustment Data Validation Protocols that we anticipate will be released in May 2019.

⁸⁹ See 83 FR at 16970–16971.

validation, unless another exemption applied.

Comment: Several commenters supported the proposals regarding exiting issuers, indicating that it would not be helpful to market stability and would cause harm to issuers that remain in a market if an exiting issuer that was a negative error rate outlier resulted in adjustments to the risk scores and transfers in the state market risk pool. A few commenters supported the proposal, and some stated that it should be extended so that no issuer's risk score or transfer would be increased for a negative error rate, stating that doing so would create significant uncertainty in financial projections and pricing for issuers.

Response: After consideration of the comments received, we are finalizing the risk adjustment data validation policies regarding exiting issuers, and will apply this policy to the 2018 benefit year risk adjustment data validation and beyond. We believe that the policies on exiting issuers mitigate the impact on remaining issuers, and will aid in the market's stability and proper functioning year to year by limiting the application of an exiting issuer's risk adjustment data validation results to situations where the issuer was overpaid or undercharged for the benefit year being validated. Comments on negative error rates generally (that is, for issuers who are not exiting issuers) are addressed in a separate section of this preamble below.

ii. Risk Adjustment Data Validation Adjustments in Single Issuer Markets

For an issuer that is the sole issuer in a state market risk pool in a benefit year, there are no risk adjustment transfers under the state payment transfer formula and thus, no payment or financial accountability to other issuers for that risk pool.⁹³ We do not calculate risk adjustment transfers for a benefit year in a state market risk pool in which there is only one issuer, and that issuer is not required to conduct risk adjustment data validation for that state market risk pool.⁹⁴ However, if the sole issuer was participating in multiple risk pools in the state during the year that is being audited, that issuer will be subject to risk adjustment data validation for those risk pools with other issuers that had risk adjustment transfers calculated. In addition, the sole issuer may have been identified as an outlier for risk adjustment data validation, and its error rate would be applied to all of its risk adjustment covered plans in the state

market risk pools where it was not the sole issuer. Its error rate would also be applied to adjust the subsequent benefit year's transfers for other issuers in the same state market risk pool(s). If the sole issuer that participated in risk adjustment data validation for a benefit year was identified as outlier, and in the following benefit year, a new issuer entered what was formerly the sole issuer risk pool, we proposed that the former sole issuer's error rate would also apply to the risk scores for its risk adjustment covered plans in the subsequent benefit year in the risk pool(s) in which had been the sole issuer—that is, the formerly sole issuer's risk scores and transfer amounts calculated for the benefit year in which a new issuer entered the state market risk pool which did not have risk adjustment transfers calculated in the prior year would be subject to adjustment based on the formerly sole issuer's error rate. In addition, the new issuer would have its risk adjustment transfer adjusted in the current benefit year if the former sole issuer was an outlier with risk score error rates in the prior benefit year's risk adjustment data validation.

Comment: A few commenters disagreed with the proposals for new entrants into a risk pool that formerly was a single issuer risk pool. These commenters stated that all issuers should be treated the same under risk adjustment data validation, and that a new entrant who was not subject to risk adjustment data validation in the year before the year in which it entered the state market risk pool should not be subject to adjustments until both issuers have undergone risk adjustment data validation. One of these commenters also expressed concerns that the proposed policy would create “perverse incentives” and decrease market stability, and that issuers would face uncertainty about future liabilities associated with risk adjustment data validation depending on whether another issuer enters the market in question.

Response: After consideration of the comments received, we are finalizing the policies related to the application of risk adjustment data validation results when there are new entrants into a risk pool that formerly was a single issuer risk pool for the 2018 benefit year risk adjustment data validation and beyond. We do not believe that this policy would create perverse incentives, decrease market stability, or cause uncertainty about future liabilities associated with risk adjustment data validation, as this policy results in consistent treatment for all issuers.

Thus, transfers will be adjusted for outliers when another issuer joins a sole issuer state market risk pool, as risk adjustment data validation is based on all state markets and outlier status in one market is reflective of outlier status in others.⁹⁵ In fact, we believe postponing the application of adjustments due to risk adjustment data validation outlier status for sole issuer state market risk pools until both issuers have undergone risk adjustment data validation possibly could create perverse incentives and result in market distortions, as issuers would not be required to substantiate their EDGE data submissions nor would the issuer identified as an outlier in other market risk pools in the state be subject to the adjustments deemed appropriate through the prior year's risk adjustment data validation. Additionally, we do not agree that issuers would face uncertainty about future liabilities associated with risk adjustment data validation depending on whether another issuer enters the state market risk pool in question. This sole issuer policy finalized in this rule is consistent with the policy established in the 2015 Payment Notice specifying that each issuer's risk score adjustment (from risk adjustment data validation results) will be applied to adjust the plan's average risk score for each of the issuer's risk adjustment covered plans.⁹⁶ This policy also aligns with how error rates are applied if a new issuer entered a state market risk pool with more than one issuer.

iii. Risk Adjustment Data Validation and Negative Error Rate Outlier Markets

As discussed in the proposed rule if an issuer is a negative error rate outlier, its risk score will be adjusted upwards. Assuming no changes to risk scores for the other issuers in the state market risk pool, this upward adjustment would reduce the issuer's risk adjustment charge or increase its risk adjustment payment for the applicable benefit year, leading to an increase in risk adjustment charges or a decrease in risk adjustment payments for the other issuers in the state market risk pool. If an issuer is a positive error rate outlier, its risk score will be adjusted downwards. Assuming no changes to risk scores for the other issuers in the state market risk pool, this downward adjustment would increase the issuer's charge or decrease its payment for the applicable benefit year, leading to a decrease in charges or an increase in payments for the other issuers in the state market risk pool. The

⁹³ See 83 FR at 16967.

⁹⁴ Id.

⁹⁵ 79 FR 13768 through 13769.

⁹⁶ 79 FR 13743 at 13768 through 13769.

intent of this two-sided outlier identification, and the resulting adjustments for outlier issuers that have significantly better than average (negative error rate) and poorer than average (positive error rate) data validation results is to ensure that risk adjustment data validation adjusts risk adjustment transfers for identified, material risk differences between what issuers submitted to their EDGE servers and what was validated in medical records. The increase to risk score(s) for negative error rate outliers is consistent with the upward and downward risk score adjustments that were finalized as part of the original risk adjustment data validation methodology in the 2015 Payment Notice⁹⁷ and the HCC failure rate approach to error estimation finalized in the 2019 Payment Notice.⁹⁸ That is, the long-standing intent of HHS-operated risk adjustment data validation has been to account for identified risk differences, regardless of the direction of those differences.⁹⁹

However, we sought comment on the impact of the current approach under the error estimation methodology and the outlier adjustment policy for negative error rate outlier issuers, or issuers with significantly lower-than-average HCC failure rates, on other issuers in a state market risk pool, the incentives that negative error rate adjustments may create, and potential modifications to the error rate estimation methodology or the outlier adjustment policy, such as to utilize the state mean failure rate instead of the

⁹⁷ For example, we stated in the 2015 Payment Notice that “the effect of an issuer’s risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market”. See 79 FR 13743 at 13769.

⁹⁸ For example, in the 2019 Payment Notice, we stated that “we will use a 1.96 standard deviation cutoff, for a 95 percent confidence interval, to identify outliers” and that “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.” We also stated that “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.” 83 FR 16930 at 16962. The shorthand “positive error rate outlier” captures those issuers whose HCC coefficients are reduced as a result of being identified as an outlier; while the shorthand “negative error rate outlier” captures those issuers whose HCC coefficients are increased as a result of being identified as an outlier.

⁹⁹ An exception to this approach is the policy finalized, beginning for the 2018 benefit year of risk adjustment data validation, and discussed above in this rule for exiting issuers who are negative error rate outliers.

national mean failure rate, to modify the error rate calculation to the confidence interval instead of the mean, to exclude negative error rate outliers or to use other methods of lessening the impact of negative error rate issuers on affected risk pools, beginning with the 2018 benefit year of risk adjustment data validation or later.

Comment: Some commenters recommended that HHS follow its current risk adjustment data validation methodology and outlier adjustment policy, beginning with the application of 2017 benefit year risk adjustment data validation to 2018 benefit year risk adjustment transfers, without further delay or material change. These commenters stated that further delay of risk adjustment data validation would be unreasonable, create market instability, and would fundamentally jeopardize the program’s integrity. These commenters also expressed support for evaluating prospective improvements to the HHS risk adjustment data validation methodology and outlier adjustment policy for future benefit years.

However, other commenters stated that issuers generally did not expect the significant financial impact of risk adjustment data validation to be as large as indicated by the 2016 pilot results that were released by HHS in July 2018,¹⁰⁰ noting that the current risk adjustment data validation error rate methodology was not finalized until April 2018. These commenters also tended to express concern that the error rates are calculated based on adjusting to the mean, instead of the confidence intervals. Some of these commenters were also concerned that issuers may begin booking anticipated impact of risk adjustment data validation on 2018 risk adjustment transfers in their 2019 financials, raising premiums due to the uncertainty associated with estimating those impacts. These commenters believe that the current risk adjustment data validation methodology would lead to higher premiums by compelling

¹⁰⁰ On July 13, 2018, HHS released a memo via Risk Adjustment Data Validation Audit Tool for issuers titled, “2016 Benefit Year HHS-operated Risk Adjustment Data Validation (HHS-RADV) Final Results” that included the program benchmark metrics and the 2016 benefit year HHS-RADV Results Job Aid report that included the HCC group definitions and an illustrative example of the steps for error rate calculation. Thus, issuers were provided with illustrative information on the 2016 benefit year risk adjustment data validation results under the methodology finalized in April 2018, but that information was provided for informational purposes only and should not have been used for purposes of rate setting. In addition, as a second pilot year, the 2016 benefit year risk adjustment data validation results were not applied to adjust risk adjustment transfers.

issuers to raise premiums to buffer against the potential of unpredictable risk adjustment data validation adjustments, which could create instability and unpredictability in rate setting, and affect market participation.

Several commenters expressed concern about the impact of the negative error rate outliers in cases where the issuer had a zero error rate, particularly given the potential distributive effect of the adjustments to transfers based on market share. Another commenter stated that the exiting issuer proposal on negative error rates should be extended to all issuers such that no issuer’s risk score would be increased because of a negative error rate. The commenter believes that this would avoid the creation of significant uncertainty in financial projections and pricing for issuers in the same state market risk pool whose transfers could be negatively affected by another issuer’s increased risk score.

One commenter questioned HHS’ authority to apply the current risk adjustment data validation error estimation methodology to 2018 risk scores. Another commenter stated its belief that HHS has the authority to make adjustments to the risk adjustment data validation methodology finalized in the 2019 Payment Notice. Some commenters suggested that HHS treat the 2017 benefit year as another pilot year or postpone the implementation of the risk adjustment data validation adjustments to risk scores and transfers until later benefit years (for example, 2020 and beyond).

Many commenters recommended HHS convene a joint industry stakeholder workgroup to develop effective solutions to ensure the risk adjustment program achieves its goals and fulfills its intended purpose. Other commenters recommended broader changes to the risk adjustment data validation process, such as using a targeted data-driven approach to risk adjustment data validation, dividing the audits into individual and small group to separate the impact on transfers, or creating a process to exempt issuers from validating HCCs for which a provider refuses to supply a medical record (when the issuer has demonstrated good faith in trying to obtain that record).

Response: We did not propose and are not making any changes with respect to the application of 2017 benefit year risk adjustment data validation results to 2018 benefit year risk adjustment risk scores and transfers using the current HHS risk adjustment data validation methodology and outlier adjustment policy. HHS conducted 2 pilot years for

risk adjustment data validation, and we agree with commenters that another pilot year would not be appropriate at this time (absent the exception for Massachusetts issuers detailed below) because further delay could jeopardize the program's integrity. Thus, we are not making the 2017 benefit year risk adjustment data validation a pilot year, nor are we making any changes to the risk adjustment data validation error estimation methodology for the 2017 or 2018 benefit years.

While the current error estimation methodology was not finalized until April 2018, it was applied prospectively to risk adjustment data validation for the 2017 benefit year. We have also been transparent about the potential for adjustments based on risk adjustment data validation results, including the two-sided nature of such adjustments, since the inception of the program. Consistent with § 153.350(c), as finalized in the final rule Standards Related to Reinsurance, Risk Corridors and Risk Adjustment,¹⁰¹ 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 covered plan due to errors discovered during data validation. This approach was also reflected in the 2014 Payment Notice, which noted our intent to make adjustments where an issuer under-reported its risk scores.¹⁰² Further, under the original risk adjustment data validation methodology finalized in the 2015 Payment Notice¹⁰³, every failure to validate an HCC would have resulted in an adjustment to the issuer's risk score and would have also affected transfers for all issuers in the state market risk pool (including both issuers with HCC validation failures and those without) due to the budget neutral nature of the HHS-operated risk adjustment program.

However, as detailed in the 2019 Payment Notice, we recognized that many issuers would experience some variation and error 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-operated risk adjustment data validation pilot years reinforced this belief. As a result, to avoid adjusting transfers for

any and all failures, we adopted the HCC failure rate methodology, which results in adjustments to an issuer's risk score only when the issuer's failure rate is statistically different from the weighted mean failure rate, or total failure rate, for all issuers that submitted initial validation audits (that is, the issuer is identified as an outlier). Similar to the original methodology finalized in the 2015 Payment Notice, when there is an outlier issuer, the transfers for other issuers in the state market risk pool will also be adjusted due to the budget neutral nature of the HHS-operated risk adjustment program. We further note that, based on our analysis of the 2016 benefit year risk adjustment data validation results and our analysis of the initial estimated 2017 benefit year risk adjustment data validation results, we have found that the HCC failure rate approach to error estimation significantly reduces the overall transfer impact of adjustments when compared with results under the original methodology.

Additionally, as detailed above, the identification of positive and negative error rate outliers and the resulting adjustments under the HCC failure rate methodology is consistent with the two-sided adjustment approach adopted under the original risk adjustment methodology finalized in the 2015 Payment Notice. Except as provided elsewhere in this final rule for negative error rate outliers resulting from exiting issuers, we continue to believe that adjusting for both negative and positive error rate outliers ensures that issuers' actual actuarial risk is reflected and that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. It also incentivizes issuers to achieve the most accurate EDGE data submissions for initial risk adjustment transfer calculations. For all these reasons, we do not believe that further changes are needed to the error estimation methodology or the outlier adjustment policy at this time. We will apply the current methodology and outlier adjustment policy to both the 2017 benefit year and 2018 benefit year of risk adjustment data validation. We intend to solicit further comments and work with stakeholders regarding potential changes for future benefit years.

However, as explained above, while issuers have been on notice since 2012 that adjustments based on risk adjustment data validation results could

occur,¹⁰⁴ we recognize that the initial experience during the pilot years of risk adjustment data validation has caused concern over the potential direction and magnitude of the adjustments. After consideration of the comments received, and further analysis of timing considerations (such as the impact on adjustments of any successful risk adjustment data validation appeals, as well as the proposed change to the risk adjustment appeals holdback for the 2018 benefit year and beyond ("Proposed Holdback Guidance"¹⁰⁵)), we are updating the timeline for publication, collection, and distribution of risk adjustment data validation adjustments to transfers. We still intend to publish 2017 benefit year error rates in May 2019, but under our updated timeline, we intend to publish the 2017 benefit year risk adjustment data validation adjustments on August 1, 2019 after the release of the Summary Report on Permanent Risk Adjustment Transfers for the 2018 Benefit Year (intended to be released on June 28, 2019). The information released in the August 1, 2019 report on risk adjustment data validation adjustments to transfers will be based on the preliminary 2017 benefit year risk adjustment data validation results, prior to the resolution of appeals. The August 1, 2019 report will also include information on 2017 benefit year default data validation charges under § 153.630(b)(10) and allocation of those amounts. We will also delay the collection and distribution of 2017 benefit year risk adjustment data validation adjustments to 2018 benefit year risk adjustment transfers and 2017 benefit year default data validation charges and allocations until 2021 to provide issuers with more options on how and when to book financial impacts from risk adjustment data validation, in keeping with guidance from state departments of insurance, where applicable. Specifically, we intend to update the Medical Loss Ratio Form Instructions to provide guidance to issuers, consistent with § 153.710(g)(2) and (3), regarding the reporting of risk adjustment data validation adjustments for medical loss ratio reporting purposes. The guidance would instruct issuers to report risk adjustment data validation adjustments and default data validation charges and allocations in the same medical loss

¹⁰¹ 77 FR 17234.

¹⁰² 78 FR at 15438.

¹⁰³ For example, we stated in the 2015 Payment Notice that "the effect of an issuer's risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market". See 79 FR 13769.

¹⁰⁴ See, Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 77 FR 17234, 2014 Payment Notice, 78 FR at 15438, and 2015 Payment Notice, 79 FR 13769.

¹⁰⁵ Available at www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Proposed-Changes-RA-Holdback-2018BY.pdf.

ratio reporting year as the year when these amounts are collected and disbursed (for example, the 2017 benefit year risk adjustment data validation adjustments and default data validation charges and allocations would be reported in the 2021 MLR reporting year). We also intend to update the Unified Rate Review Template (URRT) instructions to permit issuers and states to consider risk adjustment data validation adjustment impacts in rates for the year when these amounts will be collected and disbursed (for example, issuers and states would have the option to consider 2017 benefit year risk adjustment data validation adjustments in rate setting for the 2021 benefit year, instead of 2020 benefit year rate setting). Changing the timeline for the year in which issuers may pay, receive, and account for their results from risk adjustment data validation in the MLR and URRT submissions will only change the timing. This approach will not change the associated processes and therefore will not increase burden on issuers or states. Delaying the collection and distribution of 2017 benefit year risk adjustment data validation adjustments to 2018 benefit year risk adjustment transfers until 2021 will also allow more time for HHS to work with issuers to resolve any risk adjustment data validation appeals. It will also help mitigate the potential for additional uncertainty and instability that could be created by making adjustments before appeals are resolved, as a successful risk adjustment data validation appeal could affect the calculated risk score error rate and accompanying adjustments to transfers.

We anticipate adhering to a similar timeline in future years for the collection and payment of risk adjustment data validation adjustments to risk adjustment transfers (along with default data validation charges and allocations), such that risk adjustment transfers without risk adjustment data validation adjustments would be reported by June 30th of the year after the applicable benefit year, and issuers would report those amounts in the medical loss ratio reports submitted by July 31st of the year after the applicable benefit year. The preliminary risk adjustment data validation adjustments that could impact that benefit year's transfers, along with information on default data validation charges and allocations for the applicable benefit year, would be reported after the June 30 report is published, and we would collect and disburse risk adjustment data validation adjustments and default data validation charges and allocations

two years after the announcement. Issuers would be instructed to reflect those final adjustment amounts and default data validation charges and allocations in the medical loss ratio reporting year in which collections and payments of those amounts occur, and would be permitted to reflect those amounts in rate setting for that same benefit year. For example, 2018 benefit year risk adjustment data validation adjustments and default data validation charges and allocations would be collected and paid in 2022; issuers could account for the impacts of those amounts in rate setting for the 2022 benefit year, and issuers would report the adjustments and default data validation charges and allocations in the 2022 benefit year medical loss ratio reporting year. Furthermore, given these timeline changes for collecting and paying risk adjustment data validation adjustments being finalized in this final rule and in response to comments that we received indicating that some issuers had difficulty obtaining medical records, we are also considering options to extend the timeline for conducting and completing the risk adjustment data validation processes for issuers and HHS. We believe that this additional time may help issuers in completing the operational processes in future benefit years. Therefore, we intend to seek input on an updated risk adjustment data validation timeline beginning with the 2018 benefit year to provide more time for medical record collection during the initial validation audits and more time for the completion of the second validation audit.

Comment: Some commenters supported the current policy that involves adjusting for both positive and negative outliers with one of these commenters noting that adjustments for negative outliers encourage complete and accurate coding, and more comprehensive documentation. Many commenters, on the other hand, supported the elimination of risk score adjustments for issuers that are negative error rate outliers, noting that a negative error rate issuer should not be rewarded for submitting incorrect or incomplete data to the EDGE server and that negative error rate outliers create uncertainty in the market, particularly for issuers within the confidence bounds (that is, those issuers who are not outliers). One commenter supported adjusting an issuer's risk score when the issuer's error rate materially deviates from a statistically meaningful value or when its error rate materially deviates from a statistically meaningful value by a multiplier figure that values back to

the outlier cutoff point. Another commenter recommended that HHS apply the error rates to the transfers of the benefit year that is being audited, rather than to transfers in the following benefit year.

Several commenters recommended that outlier issuers' error rates be calculated based on the ends of the confidence interval instead of the mean to eliminate the "payment cliff" under the current methodology. Some of these commenters preferred adjusting outliers to the nearest ends of the confidence intervals as a short term solution to reduce the negative financial impact on other issuers in the state market risk pool because, for example, they believe the nationwide weighted average provides an adjustment that is too large in states where the statewide group failure rate is lower than the nationwide average. Some of these commenters also noted that adjusting to the confidence intervals would minimize unexpected impacts on transfers and remove the extreme impact of small adjustments in HCC accuracy for issuers whose failure rates are near the edges of the confidence interval.

Response: We did not propose and are not making any changes to the error estimation methodology applicable to 2017 and 2018 benefit years risk adjustment data validation. We have concerns about adjusting outlier issuers to the edges of the confidence intervals instead of the mean, which is why that approach was not adopted in the current error estimation methodology. Specifically, we are concerned that adjusting to the edges of confidence intervals may effectively reduce the impact of risk adjustment data validation results to the point that the positive error rate outlier adjustments may not provide enough disincentive to prevent inappropriate coding and the benefit of upcoding may outweigh the potential costs of the risk adjustment data validation risk score adjustments. However, in future years, after we have analyzed more data on the risk adjustment data validation results, we intend to consider refinements to the risk adjustment data validation process and methodology, and may consider alternative options for error rate adjustments, such as using multiple or smoothed confidence intervals for outlier identification and risk score adjustment. While we are interested in applying the risk adjustment data validation results to the benefit year being audited, we have concerns that in order to switch to that policy starting with the 2018 benefit year, we would be adjusting 2018 benefit year risk adjustment twice (once for the 2017

benefit year risk adjustment data validation results and a second time for the 2018 benefit year risk adjustment data validation results). However, we will continue to consider modifications to risk adjustment data validation processes and methodologies, including which benefit year transfers' the data validation adjustments are applied to, for future benefit years. As mentioned elsewhere in this final rule, we intend to consider the comments received for potential updates to the current methodology and outlier adjustment policy for future benefit years. We will consult with stakeholders before implementing any such changes.

Comment: One commenter requested that HHS treat the 2017 benefit year as a pilot year for Massachusetts for risk adjustment data validation purposes since the 2017 benefit year was the first year that Massachusetts issuers participated in the HHS-operated risk adjustment program. This commenter noted that there will be some distortion in the results of audits for issuers in Massachusetts, and was especially concerned that this distortion may be magnified for smaller issuers.

Response: We understand that Massachusetts issuers are in a unique situation with regard to risk adjustment data validation for the 2017 benefit year, since the 2017 benefit year was the first year in which Massachusetts participated in the HHS-operated risk adjustment program and submitted data to EDGE servers, and no Massachusetts issuers¹⁰⁶ had an opportunity to participate in the pilot years of HHS risk adjustment data validation. Therefore, in response to comments and after consideration of the specific facts and circumstances involved, we believe that exercising our enforcement discretion to provide Massachusetts issuers with a non-adjustment year for risk adjustment data validation is appropriate. It is consistent with our general approach to implementing risk adjustment data validation in other states where HHS is responsible for operating the program and we will therefore exercise our discretion to operate risk adjustment data validation for the 2017 benefit year as a pilot year for Massachusetts.

Massachusetts issuers will receive 2017 benefit year risk adjustment data validation error rate results, but these

issuers will not have their 2018 benefit year risk adjustment risk scores or transfers for Massachusetts state market risk pools adjusted based on 2017 risk adjustment data validation results. Furthermore, Massachusetts issuers' failure rates will not be included in the calculation of the national metrics for the 2017 benefit year risk adjustment data validation to avoid the potential distortion in the national metrics that will be applied to issuers in other state market risk pools. All other issuers in all other states and the District of Columbia will have their 2018 benefit year risk adjustment risk scores and transfers adjusted based on 2017 benefit year risk adjustment data validation results in accordance the current error estimation methodology finalized in the 2019 Payment Notice. In addition, to the extent that a Massachusetts issuer also offered risk adjustment covered plans in other state market risk pools, its 2018 benefit year risk adjustment risk scores and transfers for those other state market risk pools will be adjusted based on 2017 benefit year risk adjustment data validation results.

h. Exemptions From Risk Adjustment Data Validation

In previous rules,¹⁰⁷ we established exemptions from the HHS-operated risk adjustment data validation requirements for issuers with 500 or fewer billable member months statewide and issuers at or below a materiality threshold for the benefit year being audited. Additionally, on April 9, 2018, we released guidance indicating that we intended to propose a similar exemption from risk adjustment data validation requirements for certain issuers in or entering liquidation.¹⁰⁸ The purpose of these policies is to address numerous concerns, particularly from smaller issuers and state regulators, regarding the regulatory burden and costs associated with complying with the HHS-operated risk adjustment data validation program. HHS previously considered these concerns and provided relief where possible, and under this final rule, we are codifying these exemptions in regulation at § 153.630(g), as described further below.

In the 2019 Payment Notice, we finalized that beginning with 2017 benefit year HHS-operated risk adjustment data validation, issuers with

500 billable member months or fewer statewide in the benefit year being audited 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.¹⁰⁹ We explained that exempting these issuers from the requirement to hire an initial validation auditor is appropriate because they will 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 will not be subject to random (or targeted) sampling under the materiality threshold, and they will continue to not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. Issuers who qualify for this exemption will not be subject to enforcement action for non-compliance with risk adjustment data validation requirements, or be assessed the default data validation charge under § 153.630(b)(10). We stated that the determination of whether an issuer has 500 or fewer billable member months will be made on a statewide basis (that is, by combining an issuer's enrollment in a state's individual, small group, and merged markets, as applicable, in a benefit year). In the proposed rule, we proposed to codify this exemption at § 153.630(g)(1). We received no comments on codifying this exemption; therefore, in this final rule, we are codifying this exemption as proposed. Consistent with the finalized policy adopted in the 2019 Payment Notice, this exemption is available beginning with the 2017 benefit year of risk adjustment data validation.

Second, in the 2018 Payment Notice, HHS finalized a materiality threshold for risk adjustment data validation to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans.¹¹⁰ We evaluated the burden associated with risk adjustment data validation, particularly, the fixed costs associated with hiring an initial validation auditor and submitting results to HHS on an annual basis. We established a materiality threshold for risk adjustment data validation that considered the burden of such a process on smaller plans. Specifically, we stated that issuers with total annual premiums at or below \$15 million for risk adjustment covered plans (calculated statewide based on the premiums of the benefit year being validated) will not be subject

¹⁰⁶ Participation in risk adjustment data validation is based on HIOS IDs and not parent companies. Therefore, while some issuers' parent companies in Massachusetts may have previously participated in the HHS-operated risk adjustment program in other states under other issuer HIOS IDs, no issuer HIOS IDs in Massachusetts previously participated in the HHS-operated risk adjustment program, including the pilot years of risk adjustment data validation.

¹⁰⁷ See 81 FR 94058 at 94104 and 83 FR 16930 at 16966.

¹⁰⁸ Exemption from HHS-Operated Risk Adjustment Data Validation (HHS-RADV) for Issuers in Liquidation or Entering Liquidation (April 9, 2018). <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf>.

¹⁰⁹ 83 FR 16930 at 16966.

¹¹⁰ 81 FR 94058 at 94104–94105.

to the annual initial validation audit requirements, but will still be subject to an initial validation audit approximately every 3 years (barring any risk-based triggers due to experience that warrant more frequent audits). Under the established process, we will conduct random and targeted sampling for issuers at or below the materiality threshold, beginning with the 2018 benefit year of risk adjustment data validation. Even if an issuer is exempt from initial validation audit requirements under the materiality threshold, HHS may require these issuers to make records available for review or to comply with an audit by the federal government under § 153.620.

We proposed to codify the materiality threshold exemption at § 153.630(g)(2), providing that an issuer of a risk adjustment covered plan would be exempt from the data validation requirements in § 153.630(b) if the issuer is at or below the materiality threshold defined by HHS and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under a random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers due to experience that warrant more frequent participation in risk adjustment data validation).¹¹¹

Consistent with the materiality threshold finalized in the 2019 Payment Notice,¹¹² we proposed to define the materiality threshold as total annual premiums at or below \$15 million, based on the premiums of the benefit year being validated for all of the issuer's risk adjustment covered plans in the individual, small group, and merged markets (as applicable) in the state. We did not propose any trending adjustment to the materiality threshold, but stated that if we were to modify the definition of materiality to trend the \$15 million threshold in future benefit years, we would propose that change through notice-and-comment rulemaking.

We noted that if an issuer of a risk adjustment covered plan within the materiality threshold is not exempt from the data validation requirements for a given benefit year (that is, the issuer is selected by random and targeted sampling), and fails to engage an initial validation auditor or to submit the

results of an initial validation audit to HHS, the issuer would be subject to a default data validation charge in accordance with § 153.630(b)(10), and may be subject to other enforcement action.

We are codifying this exemption at § 153.630(g)(2), including the establishment of a \$15 million threshold that will continue to apply until such time as it may be changed through notice-and-comment rulemaking as proposed. Consistent with the original policy finalized in the 2018 Payment Notice, this exemption is available beginning with 2018 benefit year risk adjustment data validation.

Lastly, as noted in this rule, HHS released guidance on April 9, 2018 indicating our intention to propose in future rulemaking an exemption from risk adjustment data validation requirements for certain issuers in liquidation or that will enter liquidation. The purpose of exempting these issuers is similar to the reasons outlined in this rule for smaller issuers and those below the materiality threshold—to recognize the burdens and costs associated with the risk adjustment data validation requirements on these issuers, given their reduced financial and staff resources. Under this proposal, certain issuers in liquidation or that will enter liquidation would be exempt from the requirement to hire an initial validation auditor and submit initial validation audit results, as well as the second validation audit requirements, and would not be subject to enforcement action for non-compliance with risk adjustment data validation requirements or be assessed the default data validation charge under § 153.630(b)(10).

We proposed codifying at § 153.630(g)(3) that an issuer would be exempt from the applicable benefit year of risk adjustment data validation if the issuer is in liquidation as of April 30th of the year when transfer adjustments based on data validation results are made (that is, 2 benefit years after the benefit year being audited). For the 2018 benefit year and beyond, we proposed that to qualify for the exemption, the issuer must also not be a positive error rate outlier in the prior benefit year of risk adjustment data validation (that is, the issuer is not a positive error rate outlier under the error estimation methodology in the prior year's risk adjustment data validation) as outlined in proposed paragraph (g)(3)(ii). If an issuer in liquidation or that will enter liquidation by the applicable date was a positive error rate outlier in the previous year's risk adjustment data validation, we proposed not to exempt

the issuer from the subsequent benefit year's risk adjustment data validation, and the issuer would be required to participate in risk adjustment data validation or receive the default data validation charge in accordance with § 153.630(b)(10) unless another exemption applies.

To qualify for this exemption in any year, we proposed under paragraph (g)(3)(i) that the issuer must provide to HHS, in a manner and timeframe to be specified by HHS, an attestation that the issuer is in or will enter liquidation no later than April 30th 2 years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer. In proposed paragraph (g)(3)(iii), we proposed to define liquidation as meaning that a state court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest. Our intention with this policy was to align the definition of liquidation with state law on liquidation of health insurance issuers and the National Association of Insurance Commissioners' Model Act on receivership where possible.¹¹³

While we understood the exact date of a liquidation order may be uncertain in specific circumstances, we proposed that the individual signing the attestation must be reasonably certain that the issuer will enter liquidation by April 30th 2 benefit years after the benefit year being audited.

Under our proposal, we would accept an attestation from a representative of the state's department of insurance, an appointed liquidator, or other appropriate individual who can legally and financially bind the issuer. HHS would verify the issuers' liquidation status with the applicable state regulators for issuers who submitted an attestation under § 153.630(g)(3). We also proposed that, because the April 30th 2 benefit years after the benefit year being audited is after the deadline for completing the initial validation audit for a given benefit year, an issuer who submits an attestation for this exemption but is determined by HHS to not meet the criteria for the exemption would receive a default data validation charge in accordance with § 153.630(b)(10) if the issuer fails to complete or comply with the risk adjustment data validation process within the established timeframes for

¹¹¹ When selecting issuers at or below the materiality threshold for more frequent initial validation audits, we will consider the issuer's prior risk adjustment data validation results and any material changes in risk adjustment data submissions, as measured by our quality metrics. See 81 FR 94105.

¹¹² See 83 FR 16966.

¹¹³ National Association of Insurance Commissioners Model Act, Issuer Receivership Act, 2007. <http://www.naic.org/store/free/MDL-555.pdf>.

the given benefit year, unless another exemption applies.

Additionally, we noted that any issuer that qualifies for any of the three exemptions in proposed § 153.630(g) would not have its risk score and its associated risk adjustment transfers adjusted due to its own risk score error rate, but that issuer's risk score and its associated risk adjustment transfers could be adjusted if other issuers in that state market risk pool were outliers and received risk score error rates for that benefit year's risk adjustment data validation.

We are also finalizing the codification of the liquidation exemption at § 153.730(g)(3) as proposed for the 2018 benefit year. For 2017 benefit year risk adjustment data validation, we intend to work with issuers in liquidation and will exercise our enforcement discretion, where appropriate, to provide relief consistent with the criteria outlined in the April 9, 2018 guidance¹¹⁴ and the proposed rule.

Comment: Commenters generally supported the codification of a materiality exemption, but some suggested a different threshold, noting a flat materiality threshold would not account for variations across markets. Some of these commenters suggested a threshold based on a percentage of premiums (for example, issuers whose premiums account for less than 5 percent of the statewide premium). Alternatively, some commenters stated that if a flat materiality threshold is used, it should be updated in future benefit years to account for changes in market conditions. One commenter did not support the establishment of a materiality threshold that would exempt issuers from conducting risk adjustment data validation each year. This commenter stated that all issuers should be subject to the same requirements and operate on a level playing field, and if all issuers participate in risk adjustment data validation, all issuers will have audited results, which will promote overall confidence in the risk adjustment program.

Response: Although we appreciate the comments, as noted in the proposed rule, we proposed to codify the materiality exemption that was finalized in the 2018 and 2019 Payment Notices. As detailed in these prior rulemakings¹¹⁵, we believe this exemption is appropriate because the fixed costs associated with hiring an

initial validation auditor and submitting results to HHS may be disproportionately high for smaller issuers, and may even constitute a large portion of their administrative costs. Also, we estimated that issuers that cover under 2 percent of membership nationally would qualify for this exemption, so the effect of the exemption on risk adjustment data validation is not material. HHS will continue to review and analyze whether the threshold should be updated for future benefit years, but we are maintaining the current \$15 million threshold because we believe that, under current market conditions, it still delineates properly the limited group of smaller issuers of risk adjustment covered plans that is appropriate for the exemption's relief. As detailed in prior rulemakings that established this exemption, issuers who meet the materiality threshold would not be exempt from conducting risk adjustment data validation each year. Issuers meeting this exemption will be subject to random and targeted sampling to participate in risk adjustment data validation approximately every 3 years (barring any risk-based triggers due to experience that warrant more frequent participation in risk adjustment data validation), beginning with the 2018 benefit year of risk adjustment data validation. We agree with the commenter that issuers should generally be subject to the same requirements for risk adjustment data validation, but also believe there are limited exemptions that may be appropriate to address specific concerns. We believe that, for the reasons articulated above, there is adequate justification for the materiality threshold as currently structured. We are therefore finalizing the codification of the materiality threshold exemption at § 153.630(g)(2).

Comment: Commenters disagreed with the proposal to exempt certain liquidating issuers from the requirements to hire an initial validation auditor, submit initial validation audit results, and undergo the second validation audit, and from enforcement actions for non-compliance with risk adjustment data validation requirements, including the default data validation charge. One commenter stated that issuers facing liquidation might have incentives to submit inaccurate risk adjustment data given their financial pressures, and that requiring these issuers to participate in risk adjustment data validation will promote confidence in the program and the quality of the data submitted by these issuers. Two commenters had

significant concerns that some plans might find ways to take advantage of the exemption without entering liquidation. Also, in order to create a level playing field for all issuers of risk adjustment covered plans, one commenter stressed the importance of requiring all issuers to conduct risk adjustment data validation each year, since this will promote confidence in the transfers by ensuring the quality and integrity of the issuer data.

Response: While we recognize the commenters' concern that an issuer that anticipates entering liquidation may have an incentive to provide poor quality risk adjustment data, we require all issuers to attest to the accuracy, quantity and quality of their risk adjustment data after the applicable benefit year's data submission deadline during the EDGE Attestation and Discrepancy Reporting Process, and part of this attestation notes that issuers who submit false data upon which risk adjustment transfers are calculated could be subject to prosecution under the False Claims Act. HHS also has additional safeguards that help mitigate the possibility that issuers will provide poor quality data in connection with the risk adjustment program, including authority to impose a civil monetary penalty for failure to comply with risk adjustment data requirements, as well as to impose a risk adjustment default charge where an issuer failed the EDGE quality/quantity evaluation by submitting inadequate data.¹¹⁶ Further, the requirements that the attesting individual be reasonably certain that the issuer will enter liquidation and that, beginning with the 2018 benefit year, an issuer cannot be a positive error rate outlier in risk adjustment data validation for the prior benefit year are further safeguards intended to help protect against inappropriate use of the liquidation exemption. We also note that if an issuer does not enter liquidation by the applicable April 30th due date, this exemption would not be available and the issuer would be subject to a default data validation charge under § 153.630(b)(10). Therefore, we do not anticipate that issuers will inappropriately attempt to claim the exemption without entering liquidation, and have put safeguards in place to protect against situations where an issuer attempts to do so. Since the liquidation exemption is consistent with our broader policy of providing relief where appropriate to issuers with limited resources, and the concerns noted by the commenters should be ameliorated by the safeguards and

¹¹⁴ Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf>.

¹¹⁵ See 81 FR 94104 through 94105 and 83 FR 16966 through 16967.

¹¹⁶ See § 153.740(a) and (b).

enforcement authorities described above, we are finalizing the liquidation exemption for the 2018 benefit year as proposed. We intend to work with issuers who meet the criteria outlined in the April 9, 2018 guidance¹¹⁷ and the proposed rule and will use enforcement discretion, where appropriate, to exempt these issuers for 2017 benefit year risk adjustment data validation.

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

1. Definitions (§ 155.20)

We proposed to amend § 155.20 to add definitions of “direct enrollment technology provider,” “direct enrollment entity,” “direct enrollment entity application assister,” and “web-broker.” After consideration of the comments received, we are finalizing the adoption of these new definitions as proposed. For further discussion, please see the preamble to §§ 155.220, 155.221, and 155.415.

Comment: Several commenters supported the proposed definitions, in particular the distinction created between “direct enrollment technology provider” and “web-broker.” One commenter recommended the term “direct enrollment technology provider” not be included in the definition of “web-broker” to avoid potential confusion that direct enrollment technology providers are licensed as brokers. However, the same commenter agreed that direct enrollment technology providers and web-brokers should be subject to the same requirements and acknowledged the increased complexity of completely distinguishing them.

Response: “Direct enrollment technology provider” is defined as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221. This definition refers to these entities as a type of web-broker business entity, and the accompanying definition of “web-broker” similarly includes a reference to direct enrollment technology providers, for the purpose of generally extending the same requirements to direct enrollment technology providers as web-brokers, unless otherwise specified. The creation of the term “direct enrollment technology provider” and its accompanying definition was necessary

to distinguish these entities from other types of web-brokers, where appropriate. See the below preamble discussion in §§ 155.220 and 155.221 for further details.

2. General Functions of an Exchange

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

Section 1311(d)(4)(B) of the PPACA requires an Exchange to provide for the operation of a toll-free telephone hotline to respond to requests for assistance. In the 2017 Payment Notice, we explained the distinction between a toll-free call center and a toll-free hotline, for purposes of specifying the different requirements for SBE-FPs and other Exchanges.¹¹⁸ In the 2019 Payment Notice, we finalized regulations providing for a leaner FF-SHOP implementation, and have adopted that approach. In that rulemaking, we explained that the FF-SHOPs will continue to provide a call center to answer questions related to the SHOP.¹¹⁹ Currently, employers purchase and enroll their employees in new FF-SHOP coverage through issuers and through agents and brokers registered with the FFE, and no longer enroll in SHOP coverage using an online FF-SHOP platform.

Under this approach, FF-SHOP call center volume has been extremely low. Given this experience, we proposed to amend § 155.205(a) to allow SHOPs operating in the leaner fashion described in the 2019 Payment Notice to operate a toll-free telephone hotline, as required by section 1311(d)(4)(B) of the PPACA, and to eliminate the requirement to operate a more robust call center. We proposed to amend the interpretation provided in the 2017 Payment Notice of what is required to establish a toll-free hotline, as required by section 1311(d)(4)(B) of the PPACA. There, we stated that a toll-free hotline includes the capability to provide information to consumers and appropriately direct consumers to the federally operated call center or HealthCare.gov to apply for, and enroll in, coverage through the Exchange. Given that SHOPs that operate in the leaner fashion no longer offer online enrollment and to reflect the option for such SHOPs to provide a toll-free hotline, rather than a more robust call center, we proposed that a toll-free hotline include the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers

to the applicable Exchange website and other applicable resources.

The toll-free hotline provided by such SHOPs would consist of a toll-free number linked to interactive voice response capability, with prompts to pre-recorded responses to frequently asked questions, information about locating an agent and broker in the caller’s area, and the ability for the caller to leave a message regarding any additional information needed. We stated our belief that this hotline would adequately address the needs of potential FF-SHOP consumers requesting assistance, and appropriately direct consumers to services to apply for, and enroll in, FF-SHOP coverage.

Comment: A few commenters were in support of operating the call center in a leaner fashion. One commenter was not in support of the proposal, concerned that consumers would not be able to obtain timely assistance.

Response: The SHOP toll-free call center will continue to provide timely access to assistance. Consumers can immediately access pre-recorded responses to frequently asked questions along with information about locating an agent and broker in the consumer’s area. Further, the consumer can leave a message or send an email requesting any further information needed, which will be monitored daily for prompt response. Therefore, we are finalizing these changes as proposed.

b. Navigator Program Standards (§ 155.210)

Section 1311(d)(4)(K) and 1311(i) of the PPACA require each Exchange to establish a Navigator program under which it awards grants to entities to 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 premium tax credits, and cost-sharing reductions; facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. We have implemented the

¹¹⁷ Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf>.

¹¹⁸ 81 FR at 12246.

¹¹⁹ 83 FR at 16997.

statutorily required Navigator duties through regulations at § 155.210 (for all Exchanges) and § 155.215 (for Navigators in FFEs).

Further, section 1311(i)(4) of the PPACA requires the Secretary to establish standards for Navigators to ensure that Navigators are qualified, and licensed, if appropriate, to engage in the Navigator activities described in the statute. This provision has been implemented at § 155.210(b) (for all Exchanges) and at § 155.215(b) (for Navigators in FFEs).

Section 155.210(e)(9) specifies that an Exchange may require or authorize Navigators to provide assistance with a number of topics not specifically mentioned in the statute, including certain post-enrollment activities. This section specifies that Navigators operating in FFEs are authorized to provide assistance on these topics and are required to do so under Navigator grants awarded in 2018 or later.¹²⁰ To provide more flexibility related to the required duties for Navigators operating in FFEs, we proposed to amend § 155.210(e)(9) to make assistance with these topics permissible for FFE Navigators, not required, effective upon the awarding of the FFE navigator grants in 2019. We stated our belief that making assistance with these topics optional for FFE Navigators would reduce regulatory burden on FFE Navigator entities and better meet consumers' needs by allowing FFE Navigators to prioritize work according to consumer demand, community needs, and organizational resources.

We acknowledge that HHS added these duties 2 years ago to ensure the availability of more robust consumer assistance; however, since that time, there have been programmatic and health care coverage policy changes that have caused us to reflect further. We stated our belief that consumers would be better served by allowing more flexibility for Navigators to tailor their services to make the most of their resources and to fit the needs of their communities.

In the proposed rule, we emphasized that FFE Navigators would be authorized to continue to provide assistance with any of the topics listed

¹²⁰ These topics are: Understanding the process of filing Exchange eligibility appeals; understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange; the Exchange-related components of the premium tax credit reconciliation process; understanding basic concepts and rights related to health coverage and how to use it; and, referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

under § 155.210(e)(9). Under the proposed approach, if FFE Navigator grantees choose to provide any of the assistance specified in § 155.210(e)(9), we will continue to expect them to assess their communities' needs and build competency in the assistance activities in which they are engaging. It is important to note that the current FFE Navigator training for annual certification or recertification might continue to include training on some of the § 155.210(e)(9) topics. To supplement the required FFE Navigator training, we also plan to continue providing FFE Navigators with additional information related to these assistance activities through informal webinars, newsletters, and technical assistance resources such as fact sheets and slide presentations. FFE Navigator grantees that opt to carry out any of the assistance activities in § 155.210(e)(9) will be expected to draw upon these materials to ensure their staff and volunteers are adequately prepared to provide that assistance. Our proposal also retained SBE autonomy to determine whether requiring or authorizing the SBE's Navigators to perform the activities listed in § 155.210(e)(9) best meets the state's needs and resources.

We recognize that the time FFE Navigators currently spend providing assistance with the § 155.210(e)(9) topics varies.

To better understand the future impact of removing this requirement, we requested comment on how many hours per month FFE Navigator grantees and individual Navigators currently spend providing the assistance activities described at § 155.210(e)(9), what percentage of their current work involves providing these types of assistance, and how that amount of work would be impacted if providing these types of assistance would no longer be required. We also requested comment on how FFE Navigator grantees and individual Navigators might reprioritize work and spend time fulfilling their other duties, if not required to provide the types of assistance described under § 155.210(e)(9).

In addition to proposing to increase FFE Navigator flexibility with regard to the types of assistance they provide, we also proposed to provide more flexibility related to the training requirements that Exchanges establish for Navigators. Sections 155.210(b)(2) and 155.215(b)(2) establish Navigator training standards consistent with section 1311(i)(4) of the PPACA. Section 155.210(b)(2) specifies that Exchanges must develop and publicly disseminate

a set of training standards to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure expertise in several specific topic areas.¹²¹ Currently, under § 155.210(b)(2), Exchanges (including SBEs) that opt to require their Navigators to perform the assistance described in § 155.210(e)(9) must also develop and disseminate training standards related to the specific assistance areas they require under § 155.210(e)(9). Also, Navigators in FFEs currently must be trained in fifteen additional topic areas identified at § 155.215(b)(2).¹²²

To provide more flexibility related to the training requirements for Navigators, we proposed to streamline both the requirement in § 155.210(b)(2) for all Exchanges to develop and disseminate Navigator training standards on specific topics, and the list of required training topics for FFE Navigators in § 155.215(b)(2). We proposed to amend the requirement at § 155.210(b)(2) to require Exchanges to develop and publicly disseminate training standards to ensure that the entities and individuals are qualified to engage in Navigator activities, including in the four major areas currently specified at § 155.210(b)(2)(i) through (iv). This would eliminate the training requirements at current § 155.210(b)(2)(v)–(ix) that correspond to the activities outlined in § 155.210(e)(9), since those activities would no longer be required. We also proposed to replace the current list of fifteen additional FFE Navigator training topics at § 155.215(b)(2) with a cross-reference to the amended § 155.210(b)(2) topics.¹²³ In the proposed rule, we

¹²¹ These areas include: the needs of underserved and vulnerable populations; eligibility and enrollment rules and procedures; the range of QHP options and insurance affordability programs; and, the privacy and security standards applicable under § 155.260.

¹²² These areas include: information on QHPs, including benefits covered, differences among plans, payment process, rights and processes for appeals and grievances, and contacting individual plans; the tax implications of enrollment decisions; information on affordability programs; Exchange eligibility and enrollment rules and procedures; privacy and security standards, customer service standards; outreach and education methods and strategies; appropriate contact information for other agencies for consumers seeking information about coverage options not offered through the Exchange; basic concepts about health insurance and the Exchange; working effectively with individuals with limited English proficiency, and disabled, rural, underserved or vulnerable individuals; providing linguistically and culturally appropriate services; ensuring physical and other accessibility for people with a full range of disabilities; and applicable administrative rules, processes and systems related to Exchanges and QHPs.

¹²³ We note that § 155.215 also applies to non-Navigator assistance personnel, also referred to as

stated that we believe the revised regulations would be broad enough to ensure that each Navigator program fulfills the requirements described in section 1311(i) of the PPACA.

This approach would provide Exchanges greater flexibility in designing their Navigator training programs to ensure coverage of the most instructive and timely topics and to align the training with future changes in the Navigator program or the operation of the Exchanges, while still ensuring that Navigators are qualified to carry out their required duties. This additional flexibility would also allow Exchanges to focus on training areas they determine to be most relevant to the populations they serve and on the policy and operations of the Exchange in which they operate.

Furthermore, Exchanges could opt to provide more training than would be required under these proposed amendments. For example, in addition to the FFE annual Navigator training, required for Navigator certification under § 155.215(b), Navigators in FFEs are provided with training throughout the year that serves as a supplement to the annual FFE Navigator training by covering timely and appropriate training topics that might not be included in the annual FFE Navigator training. This additional training provided by FFEs, is consistent with the requirement that FFE Navigators obtain continuing education, as specified at § 155.215(b)(1)(iv), and we intend to continue this practice.

Currently, HHS provides SBEs, including SBE-FPs, the flexibility to decide whether they will require or authorize their Navigators to provide assistance on any or all of the areas described at § 155.210(e)(9). The changes that we are finalizing in this final rule do not change that flexibility. If SBEs choose to authorize or require their Navigators to provide assistance in any of the areas listed at § 155.210(e)(9), they will still be required to ensure that their Navigators are qualified to provide this assistance.

Under our amendments, any SBEs opting to authorize or require their Navigators to provide any or all of the types of assistance listed at § 155.210(e)(9) will have the flexibility to determine effective approaches to training their Navigators on performing these types of assistance based on local experience. We believe each Exchange is best positioned to determine the

training that is most appropriate for the activities of their Navigators.

These proposals are intended to increase program flexibility within Exchanges and decrease regulatory burden related to Navigator training while maintaining standards that will ensure that Navigators are sufficiently prepared to carry out all required or authorized activities. We solicited comments on these proposals and received a range of comments in favor and not in favor of finalizing this policy. Streamlining the Navigator training requirements will allow Exchanges and Navigators to prioritize their training resources on those tasks that will best serve their state markets and Exchanges. HHS will continue to provide training on all current Navigator training topics. The format of the provided training may include other methods of technical assistance, but HHS is still committed to providing training on all of the streamlined Navigator training topics. We are finalizing these changes as proposed.

Finally, we proposed allowing, but not requiring, Navigators to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker websites under certain circumstances. We are not finalizing this proposal. For further discussion of that proposal, please see the preamble to § 155.220.

Comment: We received some comments in support of the state flexibility the rule grants to SBEs to design their own training requirements. However, many commenters expressed concern about this proposal, citing the complexity of the enrollment process; the need to educate assisters on how to best serve underserved and vulnerable populations; the need to train Navigators on how to provide culturally and linguistically appropriate services; and the unique role Navigators play in helping underserved and vulnerable populations to both enroll in and use their coverage. Commenters also stated that reducing the number of mandatory training requirements may result in Navigators not being fully equipped to serve underserved and vulnerable consumers.

Response: We agree with the commenters that supported the enhanced flexibility that the rule grants to SBEs to design the training requirements that are the best fit for their states. Nothing in this final rule prohibits SBEs from choosing not to streamline their state training or certification requirements to align with the required training in the FFEs. We believe it is important to provide SBEs with enhanced flexibility and the

autonomy to design, provide, and implement the training that is the best fit for their communities.

The streamlined training requirements will still cover how to serve vulnerable and underserved consumers as a required topic, and still require that Exchanges develop and publicly disseminate a set of training standards for Navigators to ensure Navigators are qualified to engage in Navigator activities. Additionally, the required Navigator certification and recertification trainings will not be the only source of training that HHS will provide to best educate Navigators in the FFEs on the complexities of the enrollment process, how to best serve vulnerable and underserved consumers, and how to serve consumers in ways which are culturally and linguistically appropriate. In addition to the required training, HHS will continue to provide training through other channels. These channels include webinars, policy briefs, job aids, newsletters, and fact sheets. HHS is committed to providing Navigators with sufficient training, and will continue to identify and provide trainings in areas in which it may be needed.

Comment: Many commenters expressed concern that because all Navigator entities, as recipients of federal funds, must comply with section 1557 of the PPACA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and the Americans with Disabilities Act, it is essential for HHS to continue to provide training on these topics. These commenters also expressed concern that if training on these topics were no longer required, Navigators would be unable to learn how to comply with these laws. These commenters also expressed their belief that Navigators often serve consumers who have disabilities, chronic illness, or Limited English Proficiency (LEP), and stated that if how to serve these populations were no longer a required training topic, Navigators would be unable to serve these consumers effectively.

Response: We understand that Navigators must comply with anti-discrimination laws and intend to continue to provide information about this topic as part of the broader required training category for serving vulnerable and underserved consumers required training category. We interpret the requirement for training standards to ensure the entities and individuals are qualified to engage in Navigator activities related to the needs of underserved and vulnerable populations to include topics such as:

enrollment assistance personnel. However, at this time, this program is no longer in operation in the FFEs.

- An overview of anti-discrimination laws such as section 1557 of the PPACA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act and the Americans with Disabilities Act;

- Navigators' legal responsibility to comply with the above laws;
- Best practices for how to do so; and
- How to serve underserved and vulnerable consumers, including those who serve consumers who may have disabilities, chronic illness, or a Limited English Proficiency (LEP).

We will monitor implementation of the revised Navigator trainings and their impact to ensure that these underserved and vulnerable populations continue to be properly served by the Navigator program. If HHS sees significant evidence that the capacity of Navigators to serve these populations and comply with anti-discrimination laws has eroded after these changes are implemented, we are open to reconsidering our approach.

Comment: We received comments in support of the flexibility the rule grants to SBEs to choose whether their Navigators should continue to be required to provide certain types of assistance, including post-enrollment assistance, or whether that should be optional.

Response: We agree with the commenters who supported the enhanced flexibility that the rule provides. We also agree that SBEs should have the flexibility to either act in accordance with this rule by making certain types of assistance, including post-enrollment assistance, optional, or to continue to require it. We believe that SBEs, rather than the federal government, are best suited to determine the needs of the populations they serve, and how to best prioritize the work Navigators provide to meet those needs. This final rule provides SBEs with flexibility and autonomy to allocate their resources in ways that best serve the citizens of their states.

Comment: Many commenters also expressed concern about the proposal that makes providing certain types of assistance, including post-enrollment assistance, optional in the FFE. Commenters stated that the vulnerable populations that Navigators serve require ongoing assistance after enrollment and that Navigators play an important role in educating consumers on how to use insurance once they are enrolled, including their role in assisting consumers on how to file an appeal; how to report fluctuating income to the Exchange; how to reconcile their APTC; how to provide referrals to state agencies; how to

answer consumers' questions about their health plans; how to provide education to improve consumers' health literacy; how to help consumers locate providers; and how to answer billing and payment questions.

Commenters also stated that because of the trusted relationships Navigators build with consumers during the enrollment process, Navigators are best suited to provide the post-enrollment assistance that those consumers need.

We also received comments that if providing certain types of assistance, including post-enrollment assistance, became optional rather than required, consumer health literacy and health equity may be impacted.

Response: Nothing in this final rule prohibits Navigators in the FFE from providing these types of assistance. If Navigator grantees operate in areas where significant assistance in these areas is needed, those Navigator grantees retain the option to continue providing that assistance, and we would encourage them to continue to do so.

We believe that, just like in the SBEs, Navigator grantees themselves, rather than the federal government, are in the best position to determine the particular needs of the communities they serve, and the type of assistance that is required to meet those needs. We also are committed to improving health equity, and encourage Navigators to continue their important efforts to reduce health disparities in the communities which they serve.

This final rule provides Navigator grantees with flexibility to serve their consumers according to consumer demand, community needs, and organizational resources; and allows Navigators to prioritize their work accordingly.

If Navigator grantees decide to continue to provide the types of assistance that will no longer be required, they and the Exchange are required to ensure that they are appropriately trained to provide that assistance. The FFEs will continue to provide training on post-enrollment assistance via webinars, policy briefs, job aids, newsletters, fact sheets, and other resources, as needed, and urge those Navigators to review those resources and attend those trainings.

Comment: We sought comment on the amount of time Navigators spend providing the types of assistance that will no longer be required, including post-enrollment assistance. Many commenters noted that the time Navigators spent providing such assistance was manageable, and that Navigators did not want or need the flexibility the rule provides. These

commenters stated that enrollment assistance needs lessen after the conclusion of the open enrollment period, and therefore, that Navigators had the needed time to provide post-enrollment assistance.

Response: We appreciate those who submitted comments on the amount of time spent providing the types of assistance that will no longer be required, including post-enrollment assistance. We believe the needs of the populations served by Navigators are not static, and not all communities have the same needs. The resources each Navigator may have to devote to providing this assistance may vary by grantee. We believe that it is essential to provide Navigators with as much flexibility and autonomy as possible to prioritize their work according to consumer demand, community needs, and organizational resources.

Comment: Many commenters suggested that rather than making certain types of assistance, including post-enrollment assistance, optional, and streamlining the required Navigator training standards, HHS should instead allocate more funding to the Navigator program.

Response: When Exchanges were in their infancy and public awareness and understanding of coverage options was low, HHS encouraged Navigators to provide intensive face-to-face assistance to consumers. This assistance included providing certain types of assistance, including post-enrollment assistance, as a required duty. It also guided the development of our training standards in past years. Since that time, public awareness and education on options for coverage available through the Exchanges has increased. Certified application counselors, direct enrollment partners, and Exchange-registered agents and brokers serve as additional resources for education on coverage options and outreach to consumers. We believe it is appropriate to scale down the Navigator program and other outreach activities to reflect the enhanced public awareness of health coverage options through the Exchanges.

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 Navigators subject to

§ 155.215, please see the preamble to § 155.210.

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

Throughout the preamble for §§ 155.220 and 155.221, we proposed to use the term “web-broker” to refer to an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with the selection of and enrollment in QHPs offered through the Exchange, a process referred to as direct enrollment. We have used the term “web-broker” in the preamble of prior rules, as well as in guidance, and proposed to generally replace the previously used informal definition with the one proposed in this rulemaking.¹²⁴ We proposed to define “web-broker” in § 155.20 and use that term in §§ 155.220 and 155.221, where applicable, to avoid confusion. We clarified that general references to agents or brokers would also be applicable to web-brokers when a web-broker is a licensed agent or broker. We also proposed to define “direct enrollment technology providers” as a type of web-broker that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker to provide technology services to facilitate participation in direct enrollment as a web-broker under §§ 155.220(c)(3) and 155.221. The proposed definition of web-broker reflected the inclusion of direct enrollment technology providers. Therefore, references to “web-brokers” were intended to include direct enrollment technology providers, as well as licensed agents or brokers that develop and host non-Exchange websites to facilitate QHP selection and enrollment, unless indicated otherwise. Please see the preamble discussion related to § 155.221 for further details. As noted above, we are finalizing these definitions as proposed.

As described in the preamble to § 155.221, we proposed significant changes to § 155.221 to streamline and consolidate the requirements applicable to all direct enrollment entities—both

issuers and web-brokers—in one regulation. To reflect these changes, we also proposed several amendments to § 155.220. First, we proposed to move certain requirements that apply to all direct enrollment entities from § 155.220 to § 155.221. Specifically, we proposed to move the requirements currently captured in § 155.220(c)(3)(i)(K) and (L), and to amend the requirement currently in (L), which as described further below, are now at § 155.221(b)(4) and (d), respectively. We are finalizing these changes as proposed.

We proposed conforming edits throughout § 155.220 to incorporate the use of the term “web-broker,” as proposed to be defined, in applicable paragraphs to more clearly identify which FFE requirements extend to web-brokers. In the introductory text to paragraphs (a), (c), and (d), and in paragraphs (c)(1), (c)(5), (e), (f)(1), (f)(2), (f)(3), (f)(3)(i), (f)(4), (g)(1), (g)(2), (g)(2)(iii), (g)(2)(iv), (g)(4), (g)(5)(i)(A), (g)(5)(i)(B), (g)(5)(ii), (g)(5)(iii),¹²⁵ (h)(1), (h)(2), (h)(3), (i), (j)(1), (j)(3), (k)(1), (k)(2), and (l), we proposed to add a reference to web-broker each time agents or brokers are referenced, to clarify that these paragraphs also apply to all web-brokers, including direct enrollment technology providers. In paragraphs (c)(3)(i), (c)(3)(i)(A), (c)(3)(ii), (c)(4), (c)(4)(i), (c)(4)(i)(E), (c)(4)(i)(F), and (c)(4)(ii), we proposed to replace some references to “agent or broker” with references to “web-broker” to clarify when these paragraphs apply to only web-brokers, and not to other types of agents or brokers who do not host or develop a non-Exchange website to assist consumers with direct enrollment in QHPs offered through the FFEs or SBE-FPs. We also proposed to revise the section heading for § 155.220 to “Ability of States to permit agents, brokers, and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs”, as well as the section heading for paragraph (i) to similarly add a reference to web-broker. We are finalizing these changes as proposed. Please see the preamble discussion related to § 155.221 for further details on other proposed and finalized changes related to streamlining these regulations and clarifying the

requirements applicable to web-brokers and other direct enrollment entities.

We also proposed to amend § 155.220(c)(3)(i) to add a new paragraph (c)(3)(i)(K) that requires web-broker websites to comply with the applicable requirements in § 155.221 when an internet website of a web-broker is used to complete the QHP selection. We noted this new proposed requirement would also apply when an internet website of a web-broker is used to complete the Exchange eligibility application, through the existing cross reference to paragraph (c)(3)(i) in paragraph (c)(3)(ii)(A), but the applicable requirements under § 155.221 may differ depending on whether the non-Exchange website is used to complete the Exchange eligibility application or is used to complete the QHP selection. We are finalizing this amendment as proposed. Please see the preamble discussion related to § 155.221 for further details.

We also proposed to amend § 155.220(c)(3)(i) to add a new requirement at new paragraph (c)(3)(i)(L) that prohibits web-broker websites from displaying recommendations for QHPs based on compensation the web-broker, agent, or broker receives from QHP issuers. In the proposed rule, the term “compensation” would include commissions, fees, or other incentives as established in the relevant contract between an issuer and the web-broker. In the proposed rule, we recognized that web-broker websites often ask for certain information from consumers to assist with the display and sorting of QHP options on their non-Exchange websites. This may include estimated annual income, preferences regarding health care providers, prescription drugs the consumer takes, expected frequency of doctors’ visits, or other information. We also acknowledged that web-brokers sometimes display QHP recommendations or assign scores to QHPs using the information they collect. We expressed support for the development and use of innovative consumer-assistance tools to help consumers shop for and select QHPs that best fit their needs, consistent with applicable requirements. However, we noted that we believe such recommendations should not be based on compensation web-brokers, agents, or brokers may receive from QHP issuers when consumers enroll in QHPs offered through Exchanges using web-broker non-Exchange websites. We are finalizing this amendment as proposed with the following clarification in response to comments. The definition of the term “compensation” for this

¹²⁴ HHS previously defined the term “web-broker” as including an individual agent or broker, a group of agents and brokers, or a company that is interested in providing a non-Federally-facilitated Exchange website to assist consumers in the QHP selection and enrollment process as described in § 155.220(c)(3).

¹²⁵ We also proposed minor technical edits to the last sentence of paragraph (g)(5)(iii) to more closely align this provision with the language at paragraph (g)(4), which establishes similar parameters following the termination of an agent’s, broker’s, or web-broker’s agreements and registration with the FFEs.

purpose includes commissions, fees, or other incentives granted by an issuer to a web-broker, agent, or broker. The inclusion of a reference to agents and brokers in this definition more closely aligns with the intent, which was to prohibit the display of QHP recommendations based on compensation received by any of these three entities from QHP issuers. The remaining revisions to the meaning of “compensation” are intended to capture any remuneration or incentives granted by an issuer, whether they be granted pursuant to the terms of a written contract or otherwise.

We also proposed to amend § 155.220(c)(4)(i)(A) to require a web-broker to provide HHS with a list of the agents or brokers who, through a contract or other arrangement, use the web-broker’s non-Exchange website to assist consumers with completion of QHP selection or for the Exchange eligibility application, in a form or manner to be specified by HHS. We explained that authority currently exists for HHS to request this information for agents or brokers who, through a contract or other arrangement, use the non-Exchange website to complete the QHP selection process.¹²⁶ However, due to the trend of increased use and expansion of direct enrollment pathways for QHP enrollment, we explained that we believe it was appropriate to collect this information proactively and to also extend its collection to include the use of web-broker non-Exchange websites for completion of the Exchange eligibility application, so that we may investigate and respond more efficiently and effectively to any potential instances of noncompliance that may involve agents or brokers using a web-broker’s direct enrollment pathway. Having this information would, for example, enable us to identify more quickly whether noncompliance is attributable to a specific individual or individuals, instead of the web-broker entity. We explained that we anticipate issuing further guidance on the form and manner for these submissions and were considering requiring the list must include, at minimum, each agent’s or broker’s name, state(s) of licensure, and National Producer Number. We further noted that we were considering adopting quarterly or monthly submission requirements, except for the month before the individual market open enrollment period and during the individual market open enrollment period, during which we were considering adopting weekly or daily

submission requirements. We noted we were also considering requiring the submission of this data via email using an encrypted file format, such as a password-protected Excel spreadsheet, or alternatively requiring submission through a secure portal. We invited comments on the frequency and manner for these submissions, as well as other data elements that we should consider for inclusion as part of this required reporting. We also proposed to remove the final clause in § 155.220(c)(4) that limits the scope of that section to agents or brokers using web-broker websites who are listed as the agent of record on the enrollments. Several years of experience observing web-broker operations has informed us that web-brokers often submit an entity-level National Producer Number for all QHP enrollments completed through their websites. Therefore the web-broker business entity is the agent of record. However, the requirements stated in § 155.220(c)(4) are intended to apply broadly to agents or brokers using web-broker non-Exchange websites to assist with QHP selections and enrollments. We explained that we believe the existing requirements for web-brokers that provide access to their non-Exchange websites to other agents and brokers, such as verifying agents or brokers are licensed in the states in which they are assisting consumers and have completed the FFE registration process (see § 155.220(c)(4)(i)(B)), as well as reporting to HHS and applicable state departments of insurance any potential material breaches of applicable § 155.220 standards (see § 155.220(c)(4)(i)(E)), should apply broadly to agents and brokers using web-broker non-Exchange websites, and not only to those listed as the agents of record. We are finalizing the changes to § 155.220(c)(4)(i)(A) as proposed. We intend to issue guidance regarding the form and manner for submission of information by web-brokers to HHS regarding the agents or brokers who use the web-broker’s non-Exchange website to assist with the completion of QHP selection or the Exchange eligibility application.

Currently, § 155.20 defines an “agent or broker” as a person or entity licensed by the state as an agent, broker, or insurance producer. Under § 155.220(d), an agent or broker that enrolls individuals in QHPs in a manner that constitutes enrollment through the Exchange or assists individuals with applying for APTC or cost-sharing reductions must execute an agreement with the Exchange, register with the Exchange, receive training, and comply

with the Exchange’s privacy and security standards. When these regulatory provisions were originally drafted, it was anticipated that agents and brokers were predominantly individuals. However, with the expansion of direct enrollment, there are more FFE agents and brokers, including web-brokers, that have obtained FFE registration in their capacities as licensed business entities, and not in their individual capacities as licensed agents or brokers (non-individual entities). As noted in the proposed rule, certain regulatory requirements, such as those regarding training are less suited for these non-individual types of licensed agents or brokers. For example, to comply with the requirement to complete training at § 155.220(d)(2), we currently require agents or brokers that are registered with the FFEs as non-individual entities to designate an individual to take training on the entity’s behalf, even though all individual agents or brokers assisting FFE consumers through the entity have to complete the training as individual agents and brokers. Because the training is not designed for representatives of a non-individual entity who are not providing direct assistance to FFE consumers, we explained that we believed it is appropriate to remove this requirement for licensed agent or broker non-individual entities. Therefore, we proposed to amend § 155.220(d)(2) to exempt from the training requirement a licensed agent or broker entity that registers with the FFE in its capacity as a business organized under the laws of a state, and not as an individual person. We also explained that we did not intend for this change to alter the requirement that individual agents or brokers must complete training, as applicable, as part of the annual FFE registration process. Therefore, all individual agents and brokers interacting with individual market FFE or SBE–FP consumers, whether working independently or with a non-individual agent or broker entity, including web-brokers, would continue to be required to complete annual training. Individual agents or brokers interacting with FFE–SHOP or SBE–FP–SHOP consumers would continue to be encouraged to take FFE training on an annual basis. We also proposed to include language in § 155.220(d)(2) to clarify that direct enrollment technology providers will not be required to complete FFE annual training because these non-individual entities will not be interacting with individual market FFE or SBE–FP consumers without the assistance of an individual agent or broker; they are

¹²⁶ See § 155.220(c)(4)(i)(A).

another example of a non-individual entity for which this training requirement is less suited. We are finalizing these amendments as proposed.

To improve program integrity, we proposed to delete the existing § 155.220(g)(3) and add new paragraphs (g)(3)(i) and (ii) to allow HHS to immediately terminate an agent's or broker's agreement with the FFEs for cause with notice to the agent or broker if an agent or broker fails to comply with the requirement to maintain the appropriate license under state law in every state in which the agent or broker actively assists consumers with selecting or enrolling in QHPs offered through the FFEs or SBE-FPs. We noted that the FFE agreements required under §§ 155.220(d) and 155.260(b) that agents and brokers execute with the FFEs as part of the annual FFE registration process include the requirement to maintain valid licensure in every state that the agent or broker assists Exchange consumers. State licensure as an agent, broker, or insurance producer is a critical consumer protection to ensure that when assisting Exchange consumers these individuals and entities are familiar with rules and regulations applicable in all states in which they provide assistance to FFE or SBE-FP consumers. Licensure in every state where the agent or broker is actively assisting FFE or SBE-FP consumers is a predicate requirement to registering with the FFEs to provide such assistance. We explained that allowing for immediate termination of an agent's or broker's agreements with the FFEs for failure to adhere to the applicable state licensure requirements ensures that an unlicensed individual may not continue to possess the agent/broker role that enables access to the FFEs or SBE-FPs to provide assistance to Exchange consumers as an agent or broker during the advance 30-day notice period that would otherwise apply under the current § 155.220(g)(3). We explained that we believed allowing for immediate termination in these circumstances is appropriate to protect consumers, as well as Exchange operations and systems. Under this proposal, we would confirm information about licensure (or the lack thereof) with the applicable state regulators prior to taking action under the new paragraph (g)(3)(ii). In addition, we proposed that an agent or broker whose agreements with the FFEs are immediately terminated for cause under the new proposed paragraph (g)(3)(ii) would be able to request reconsideration under § 155.220(h). We further proposed

amendments to paragraph (g)(4), such that, consistent with other terminations for cause under paragraph (g)(3), immediate terminations under the new proposed paragraph (g)(3)(ii) would result in the agent or broker not being registered with the FFEs or permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in QHPs through the FFEs or SBE-FPs or assist individuals in applying for APTC and cost-sharing reductions (CSRs) for QHPs after the applicable period has elapsed. However, in these circumstances, the agent or broker would be required to continue to protect any personally identifiable information accessed during the term of his or her or its agreements with the FFEs. We also proposed to create a new paragraph (g)(3)(i) to retain the existing language describing the current notification process and timelines for termination for cause under paragraph (g) with advance 30-days' notice, except that we proposed a clarifying edit to reflect that the new paragraph (g)(3)(ii) would constitute an exception to the current process described in existing paragraph (g)(3). As detailed earlier in this preamble, we also proposed to add a reference to web-broker to the existing paragraph (g)(3) (proposed as new paragraph (g)(3)(i)) to clarify this paragraph also applies to web-brokers. We are finalizing these amendments as proposed.

To promote information technology system security in the FFEs and SBE-FPs, including the protection of consumer data, we proposed to amend § 155.220(k) by adding a new paragraph (k)(3) that would continue to allow HHS to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction. We noted that this proposed language was identical to an existing provision that applies when an internet website of an agent or broker is used to complete QHP selection at current § 155.220(c)(3)(i)(L)¹²⁷ and a similar provision applicable to QHP issuers participating in direct enrollment at current § 156.1230(b)(1).¹²⁸ In proposed

¹²⁷ This provision also currently applies when an internet website of an agent or broker is used to complete the Exchange eligibility application through the existing cross reference to paragraph (c)(3)(i) in § 155.220(c)(3)(ii)(A).

¹²⁸ As described elsewhere in this rule, we are finalizing the proposed deletion of

§ 155.220(k)(3), we noted our intent for this provision to apply to agents and brokers who, once registered under § 155.220(d)(1), obtain credentials that provide access to FFE systems that may be misused in a manner that threatens the security of the Exchange's operations or information technology systems. We explained that we believe this proposed change was necessary to ensure that HHS can continue to take immediate action to stop unacceptable risks to Exchange operations or systems posed by agents and brokers. Because the potential risks posed by agents and brokers with access to FFE systems are similar to those posed by web-brokers or QHP issuers participating in direct enrollment, we explained that we believe this change was necessary and appropriate to provide a uniform process and ability to protect Exchange systems and operations from unacceptable risks, as well as to protect sensitive consumer data. We noted that agents and brokers whose ability to transact information with the Exchange is suspended under this proposed authority would remain registered with the FFEs and authorized to assist consumers using the Marketplace (or side-by-side) pathway,¹²⁹ unless and until their agreements are suspended or terminated under § 155.220(f) or (g). We are finalizing this change as proposed.

To further improve program integrity, we proposed in a new § 155.220(m) several additional areas in which we proposed to regulate web-brokers differently from agents or brokers. We explained that we believe these additional proposed changes in new paragraph (m) are important to further protect against potential fraudulent enrollment activities, including the improper payment of APTC and CSRs, to safeguard consumer data and Exchange operations and systems, and to ensure direct enrollment remains a safe and consumer-friendly enrollment pathway.

At § 155.220(m)(1), we proposed to allow a web-broker's agreement(s) to be suspended or terminated for cause under § 155.220(g), or a web-broker to be denied the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), based on the actions

§§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) and replacement with similar authority in § 155.221(d) that will be applicable to all direct enrollment entities.

¹²⁹ For more information on the Marketplace pathway, please see the Health Insurance Marketplace Guidance: Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplace (November 8, 2016) Available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Role-of-ABs-in-Marketplace_Nov-2016_Final.pdf.

of its officers, employees, contractors, or agents. For example, if the actions of such individuals or entities are in violation of any standard specified in § 155.220, any terms or conditions of the web-broker's agreements with the FFEs, or any applicable federal or state statutory or regulatory requirements, whether or not the officer, employee, contractor, or agent is registered with the FFEs as an agent or broker, the web-broker's agreement(s) may be terminated under paragraph (g)(3) if HHS determines the specific finding of noncompliance is sufficiently severe. Similarly, if HHS reasonably suspects that an officer, employee, contractor, or agent of a web-broker may have engaged in fraud, whether or not such individual or entity is registered with the FFEs as an agent or broker, HHS may temporarily suspend the web-broker's agreement(s) for up to 90 days consistent with § 155.220(g)(5)(i)(A).

At § 155.220(m)(2), we proposed to allow a web-broker's agreement to be suspended or terminated under § 155.220(g) or to deny it the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), if it is under the common ownership or control, or is an affiliated business, of another web-broker that had its agreement suspended or terminated under § 155.220(g). In general, for purposes of this provision, we proposed to define "common ownership or control" based on whether there is significant overlap in the leadership or governance of the entities. We also proposed to collect data during the web-broker onboarding process to assist with the analysis of whether the web-broker is under the common ownership or control, or is an affiliated business, of another web-broker that had its agreement suspended or terminated under § 155.220(g).

At § 155.220(m)(3), we proposed allowing the Exchange to collect information from a web-broker during its registration with the Exchange, or at another time on an annual basis, in a form and manner to be specified by HHS, sufficient to establish the identities of the individuals who comprise its corporate leadership and to ascertain any corporate or business relationships it has with other entities that may seek to register with the FFE as web-brokers. We explained these provisions were important to maintain program integrity, because they will provide authority to collect information that will be used to minimize the risk that an individual or entity can circumvent an Exchange suspension or termination or other enforcement action related to non-compliance. We are

finalizing the amendments to create new paragraphs (m)(1), (m)(2), and (m)(3) as proposed.

As noted in the proposed rule, the use of direct enrollment through websites other than HealthCare.gov has expanded, as have the requirements on web-brokers seeking to participate in FFEs and SBE-FPs. For those reasons, we proposed to modify prior policy that prohibited Navigators and certified application counselors (together referred to here as "assisters") from using web-broker websites to assist with QHP selection and enrollment. Our proposal would have permitted, but not required, assisters in FFEs and SBE-FPs, to the extent permitted by state law, to use web-broker websites to assist consumers with QHP selection and enrollment, if the website met certain conditions designed to ensure that assisters were able to use it while still meeting their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers. To promote state flexibility and autonomy under this proposal, SBEs other than SBE-FPs would have had discretion to permit their assisters to use web-broker websites, so long as the web-broker websites that assisters were permitted to use in SBEs, at a minimum, adhered to the standards outlined in the proposal. Also, SBEs could instead have chosen to preserve the prohibition on assister use of web-broker websites.

The expansion of direct enrollment and the implementation of enhanced direct enrollment increased interest in allowing assisters to use web-broker websites to assist consumers with selection and enrollment in QHPs offered through Exchanges. As detailed in the proposed rule, some web-brokers supported this idea, because of the unique role assisters serve in many communities. Some assisters also expressed a desire to use web-broker websites to provide an improved consumer experience by leveraging unique consumer assistance tools many web-brokers developed, such as those that provide access to real-time information on the status of submitted applications and enrollments.

In the proposed rule, we explained that the implementation of enhanced direct enrollment by some web-brokers also presents consumers with an additional method of applying for insurance affordability programs, selecting and enrolling in QHPs offered through Exchanges, and receiving post-enrollment support services. We explained that we believe this new option should be available to all FFE and SBE-FP assisters who provide

application and enrollment assistance, provided that the information and assistance the assister provides will remain fair, accurate, and impartial. We also expressed hope that allowing FFE and SBE-FP assisters to use web-broker websites to enroll consumers would encourage collaboration between assisters and web-brokers to the benefit of consumers by providing consumers the most appropriate support at each stage of the Exchange application and QHP selection and enrollment processes. To further support the use of web-broker websites by assisters, we also proposed to amend and replace § 155.220(c)(3)(i)(D) with new requirements for web-broker websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), for such websites to be eligible for use by assisters when otherwise permitted under state law. For FFEs and SBE-FPs, we proposed an optional annual certification process for web-brokers that would have been integrated into the existing annual web-broker registration process, or could have occurred during another time of year, during which a web-broker could have been certified by the Exchange by attesting to its compliance with the QHP data display requirements. We also proposed that if a web-broker website did not facilitate enrollment in all QHPs, it would be required to identify to consumers the QHPs, if any, for which the web-broker website did not facilitate enrollment by prominently displaying a standardized disclaimer provided by the Exchange, in a form and manner specified by the Exchange, stating that the consumer could enroll in such QHPs through the Exchange website, and display a link to the Exchange website. However, after consideration of comments, we are not finalizing the proposed modification to the prior policy that prohibited assisters from using web-broker websites or the accompanying proposals to amend and replace § 155.220(c)(3)(i)(D). The current policy, which prohibits the use of web-broker websites by assisters, remains in effect. We are also retaining the existing requirement at § 155.220(c)(3)(i)(D), which requires the display of all QHP data provided by the Exchange on non-Exchange websites used to complete QHP selection and/or the Exchange eligibility application.

The following is a summary of the comments received on the proposed amendments, policies and clarifications related to § 155.220. Comments related to the accompanying proposals under § 155.221 are discussed later in this rule.

Comment: Commenters that referred to the proposal at § 155.220(c)(3)(i)(L) to prohibit web-broker websites from displaying QHP recommendations based on compensation an agent, broker, or web-broker receives from QHP issuers unanimously supported it. Some commenters also supported prohibiting implicit recommendations based on compensation received from issuers by requiring web-broker websites to display all QHP information provided by the Exchange for all QHPs offered through the Exchange instead of displaying limited details and a standardized disclaimer as permitted under § 155.220(c)(3)(i)(A). One commenter recommended requiring web-broker websites to display the rationale for any QHP recommendations they make.

Response: We are finalizing the amendment as proposed at § 155.220(c)(3)(i)(L). As stated above, we are amending the definition of the term “compensation” for this purpose to include commissions, fees, or other incentives provided by a QHP issuer to the agent, broker, or web-broker. This better aligns with our intent, as well as comments received in support of the proposal, to prohibit the display of QHP recommendations on web-broker websites based on compensation an agent, broker, or web-broker receives from QHP issuers. While we acknowledge that web-broker websites may implicitly recommend QHPs based on compensation they receive from QHP issuers, we did not propose and are not establishing standards in this final rule in this regard. However, we intend to monitor implementation and effectiveness of the new standard finalized at § 155.220(c)(3)(i)(L), which prohibits the display of QHP recommendations on web-broker websites based on compensation received from QHP issuers, and may consider proposing additional standards related to the display of QHP recommendations on web-broker websites, including requiring the display of a rationale for any QHP recommendations, in future rulemaking.

We also clarify that under § 155.220(c)(3)(i)(A), a web-broker website used to complete QHP selection or the Exchange eligibility application must disclose and display all QHP¹³⁰

information provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c). If not directly provided by the Exchange, a web-broker may obtain additional information on QHPs displayed on its website directly from those QHP issuers with whom it has a contractual relationship. In accordance with § 155.220(c)(3)(i)(A), if a web-broker does not have access to all of the comparative information required under § 155.205(b)(1) and (c) for a QHP offered through the Exchange, such as premium or benefit information, it must display the required standardized Plan Detail Disclaimer for the specific QHP.¹³¹

Comment: Several commenters supported the proposal at § 155.220(c)(4)(i)(A) to require web-brokers to provide HHS with a list of agents and brokers who enter into a contract or other arrangement to use the web-broker’s website to assist consumers with Exchange applications and QHP selections. One commenter recommended the list be required annually and limited to include agents and brokers who have a signed agreement and actually used a web-broker’s website to assist with QHP enrollment in the past year, and not any agents or brokers that could potentially have used the web-broker’s website for that purpose but did not, in the interest of reducing burden. Another commenter expressed concern about the scope of this proposal and whether it extends beyond agents and brokers using a web-broker’s website to business development partners through which it receives referrals.

Response: We are finalizing the amendment as proposed at § 155.220(c)(4)(i)(A). As indicated above, we intend to issue guidance on the form and manner for these submissions and appreciate the desire to minimize the burden of this requirement. That is one of the reasons we are considering adopting a measured, targeted approach to reporting that would reduce the frequency of the submissions for most of the year by adopting quarterly or monthly submission requirements. We continue to believe that more frequent reporting, such as daily or weekly submissions, are more appropriate for the time period spanning from the

month before through the entire individual market open enrollment period because of the increased volume of enrollments and the accompanying increased access to FFE systems and consumer information during this time. For this requirement to enable us to more efficiently and effectively investigate and respond to instances of noncompliance, including those situations that may pose risks to Exchange data and systems, we must have the information more frequently than annually. For example, agents, broker, and web-brokers may enter into new relationships and/or end existing agreements at any time during the year. The adoption of an annual reporting schedule would not capture these changes until the following year. As such, there is a risk that the data would become obsolete quickly, hindering our oversight and enforcement efforts. For these reasons, we decline to adopt an annual reporting schedule.

We also believe the data collected must include information about all agents and brokers that are able to use a web-broker’s website for direct enrollment, whether or not they have done so recently, since agents and brokers with this access are equally able to access the systems and engage in misconduct that we may need to investigate. In terms of the scope of information that will have to be reported, we clarify it extends only to those agents and brokers that have a current contractual or other arrangement with a web-broker to use its website to assist consumers with the completion of an Exchange eligibility application or QHP selection in the FFE or SBE–FP. Persons or entities only referring consumers to the web-broker’s website would not be subject to this requirement.

Comment: Several commenters supported the proposal at § 155.220(g)(3)(ii) to allow for the immediate termination of agreements with agents or brokers for cause if an agent or broker fails to maintain the appropriate state license in every state in which the agent or broker is actively assisting consumers with Exchange applications and QHP enrollment. One commenter pointed out that some national licensure databases contain inaccuracies and it is important to ensure accurate information is used as the basis for termination. Another commenter emphasized the importance of timely and accurate communication between HHS and state regulators as it relates to this proposal.

Response: We are finalizing the amendments to § 155.220(g)(3) as proposed. We appreciate the comments

¹³⁰ With some limited exceptions, stand-alone dental plans (SADPs) are considered a type of QHP. See Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule (77 FR 18310, 18315) (March 27, 2012). The same display requirements extend to SADPs, including display of all applicable SADPs offered through the Exchange and

all available information specific to each SADP on their websites, as well as including the Plan Detail Disclaimer to the extent that all required SADP comparative information is not displayed on the web-broker’s website.

¹³¹ <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-Web-brokers-Displaying-Disclaimers.pdf>.

expressing concerns about the potential for inaccurate data and the need for timely communications with state regulators. We will develop procedures to verify state licensure with applicable state regulators, which may include confirming national database information with information made publicly available by individual states, as well as outreach to state regulators. We also will continue our general efforts to coordinate oversight activities related to agents and brokers with states. In addition, as detailed above, agents or brokers whose agreements with the FFEs are immediately terminated under the new paragraph (g)(3)(ii) will be able to request reconsideration under § 155.220(h).

Comment: We received several comments on the proposals at § 155.220(m) related to the enforcement actions that may be taken against web-brokers. One commenter supported the proposals. One commenter requested we clarify the use of “agent” in proposed § 155.220(m)(1), relating to the suspension or termination of a web-broker’s agreement with the Exchange under paragraph (g), and the denial of the right for the web-broker to enter into agreements with the FFE under paragraph (k)(1)(i) based on the actions of its officers, employees, contractors or agents (regardless of whether these individuals are registered with the Exchange as an agent or broker). Another commenter expressed concern that these proposals appeared to provide authority to suspend or terminate a web-broker’s agreement based on the actions of as few as one agent using the web-broker’s website. A fourth commenter stated that the proposals should apply to non-web-broker agent or broker business entities and not only web-broker business entities, and that HHS should provide examples of the actions that could be grounds for termination or suspension of a web-broker’s agreements, including whether such actions would need to be related to the operation of the web-broker’s website.

Response: We are finalizing these amendments as proposed.

As explained in the proposed rule, the intent of these changes is to provide additional tools for HHS to guard against fraudulent activities, protect consumer data and Exchange operations and systems, and address serious cases of misconduct. Web-broker business entities participating or seeking to participate in direct enrollment are proliferating. In addition, the complexity of web-brokers’ technical integrations with Exchange systems are increasing, providing greater access to sensitive consumer data and growing

dependencies between Exchange and web-broker systems. After several years of experience observing web-broker operations and participation in the FFEs and SBE-FPs, we found it was necessary to update our oversight and enforcement authority to add tools to combat fraud to align with these changes.

We do not expect this authority will be used against the vast majority of web-brokers that make a good-faith effort to comply with applicable requirements. Further, we anticipate these provisions will have limited impact as they are designed to provide HHS greater flexibility to address the limited instances where there is evidence of significant misconduct or non-compliance by a web-broker, its officers, employees, contractors, or agents. We clarify that “agent” as referred to in § 155.220(m)(1) is intended to refer to an individual or entity with a business relationship with a web-broker such that the entity or individual is authorized to act on behalf of the web-broker. “Agent” in this context may or may not refer to a licensed agent or broker registered with the FFEs to assist Exchange consumers, unless the licensed agent or broker is also authorized to act on behalf of the web-broker. We believe this new authority will close some current gaps in oversight of web-brokers, such as those that exist when an individual or entity registered with the FFEs is denied the right to enter into FFE agreements for future benefit years under § 155.220(k)(1)(i) due to misconduct and the individual or entity tries to avoid the implications of the enforcement action by creating a new web-broker business entity that seeks to register with the FFEs before the expiration of the penalty under § 155.220(k)(1)(i). Examples of the types of activities that could give rise to enforcement action under these new authorities are a web-broker’s officer instructing his agent/broker employees to falsify data submitted on consumers’ Exchange applications, a documented pattern by a web-broker entity of misusing Exchange consumer data, or the failure to adopt procedures to properly secure data and comply with applicable privacy and security requirements. As these examples illustrate, the activities for which an enforcement action may be taken under this authority are not limited to activities related only to the operation of a web-broker’s website.

While each enforcement action is fact-specific, we generally clarify that if a registered agent or broker is believed to have engaged in noncompliance that we discover through our oversight of web-broker websites, and there is no

evidence that the web-broker was part of the noncompliance activities, we would take the enforcement action against the agent or broker (and not the web-broker). However, if the investigation reveals facts that indicate the web-broker was involved in the non-compliance, then we may also take action under this new authority against the web-broker (in addition to taking appropriate action for the agent or broker involved). We may consider expanding this authority to non-web-broker agent or broker business entities in the future. However, the specific concerns and potential risks the proposals were intended to mitigate are posed most acutely by web-brokers by virtue of the more direct and expansive access they have to Exchange systems and consumer data. Therefore, we proposed and are finalizing this authority as limited to web-brokers at this time.

Comment: Numerous commenters opposed the proposal to allow assisters to use web-broker websites and the proposed new regulations that would have replaced the existing § 155.220(c)(3)(i)(D). Commenters were concerned about whether assisters could remain fair and impartial if they were assisting consumers using web-broker websites that did not offer enrollment into all QHPs offered through the Exchange, or that included QHP recommendations. Some commenters highlighted the confusion assisters and consumers may encounter when using web-broker websites that include marketing for non-QHP products. One commenter opposed any proposed expansion to the role of assisters.

Some commenters supported prohibiting web-broker websites from recommending QHPs if this proposal was finalized. One commenter suggested that assisters should only be permitted to use web-broker websites that exclusively market QHPs, and web-brokers should not receive commissions for consumers enrolled in QHPs through a web-broker website if the consumers received support from assisters. Another commenter advocated for mandatory certification of web-broker websites before assisters may use them. One commenter supported requiring web-broker websites to develop a separate pathway exclusively for assisters to use. One commenter recommended allowing web-brokers to compensate assisters to supplement federal funding for assisters, and noted that the compensation should be unrelated to whether the web-broker received a commission associated with the assistance provided to the consumer by the assister, and should include

compensation for assistance provided to consumers who are determined eligible for Medicaid.

Some commenters supported specific elements of the proposal. Several commenters supported the flexibility proposed to be provided to SBEs, other than SBE-FPs, to either permit their assisters to use web-broker websites or to instead preserve the prohibition on assister use of these non-Exchange websites. One commenter supported the proposed requirement that web-broker websites display all QHP data provided by the Exchange before assisters could use the websites. One commenter that generally supported the proposal described a potential outcome of the proposal would be the development of new consumer-assistance tools that assisters would be able to leverage when using a web-broker website to assist consumers.

Response: We agree with commenters that there are concerns related to assister use of web-broker websites that warrant further consideration, and therefore, we are not finalizing the proposed modification to the prior policy that prohibits assisters from using web-broker websites or the accompanying proposals to amend and replace § 155.220(c)(3)(i)(D) at this time. Adoption of approved enhanced direct enrollment functionality by web-brokers remains limited and we have decided to focus on the implementation and oversight of the enhanced direct enrollment pathway before allowing the use of web-broker websites by assisters. This approach also allows web-brokers interested in participating in enhanced direct enrollment to focus on implementing and complying with those new requirements at this time. In addition, new insights may be gained about how best to approach and implement this policy change as more web-brokers are approved to participate in enhanced direct enrollment and we gain more experience with enhanced direct enrollment pathways generally. We intend to monitor these changes and may revisit the current policy regarding assister use of these websites including comments received on the policies in the proposed rule, at a later date. We believe assisters remain a critical component of the options available for consumers to receive support completing the Exchange eligibility application and selecting and enrolling in QHPs, especially for certain vulnerable populations that have historically unmet needs. The current policy, which prohibits the use of web-broker websites by assisters, remains in effect and we are also retaining the

existing requirement at § 155.220(c)(3)(i)(D).

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

Direct enrollment is a mechanism for third parties to directly enroll consumers seeking QHPs through a non-Exchange website in a manner considered to be through the Exchange. Direct enrollment was created to provide consumers different options to shop for and enroll in QHPs offered through the Exchange. The entities that have been authorized to offer direct enrollment pathways to date are QHP issuers, as well as agents and brokers that develop and host non-Exchange websites to facilitate consumer selection of and enrollment in QHPs, referred to as web-brokers. As described above, in this rule we finalized a new definition for the term “web-broker.” Consistent with this new definition, we use the term web-broker throughout this final rule when we are referring to agents and brokers that develop and host non-Exchange websites to facilitate consumer selection of and enrollment in QHPs offered through an Exchange, otherwise known as direct enrollment, as well as direct enrollment technology providers. The original version of direct enrollment, or classic direct enrollment, is still in operation. It utilizes a double redirect from a direct enrollment entity’s website where QHP shopping occurs, to HealthCare.gov where the eligibility application is completed, and back to the entity’s website to finalize the selection of the QHP. Classic direct enrollment allows QHP issuers and web-brokers who meet applicable requirements to design and host a plan shopping experience, and assist consumers with the QHP selection process using relatively simple and limited application programming interfaces (APIs). The FFE direct enrollment program has expanded beyond the classic (that is, double-redirect) direct enrollment pathway as the FFEs’ technical capabilities have significantly increased, beginning with proxy direct enrollment for plan year 2018¹³² and continuing with the implementation of enhanced direct enrollment for plan year 2019 and beyond.¹³³ The requirements and

¹³² Proxy direct enrollment was implemented on a temporary basis for plan year 2018. More information is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-for-the-Proxy-Direct-Enrollment-Pathway-for-2018-Individual-Market-Open-Enrollment-Period.pdf>.

¹³³ 81 FR at 94118.

technical expertise needed to participate in each new iteration of direct enrollment have similarly increased as participants have greater access to and responsibility for sensitive consumer data and Exchange systems. With enhanced direct enrollment, HHS allows participants to create and host a dynamic eligibility application and integrate several new APIs that facilitate eligibility determinations, as well as the consumer’s enrollment in a QHP, and data sharing with the applicable Exchange. Enhanced direct enrollment provides new options for consumers to receive more comprehensive services through a non-Exchange website, without the need to redirect to HealthCare.gov, for application and enrollment and ongoing support throughout the plan year. We explained in the proposed rule that we believe this will promote innovation and competition, and ultimately lead to better experiences for more consumers. We also noted that streamlining and consolidating regulatory requirements, when possible, will simplify the otherwise complex requirements to participate in direct enrollment and make it easier for direct enrollment entities and organizations interested in participating in direct enrollment to understand and comply with applicable requirements. We also explained that the complex and evolving nature of direct enrollment requires updates to accommodate innovation, ensure program integrity, and protect sensitive consumer data.

As detailed in the proposed rule, the entities that have been permitted to offer direct enrollment pathways to date have been QHP issuers and web-brokers that develop and host non-Exchange websites to facilitate selection of and enrollment in QHPs offered through an FFE or SBE-FP. Direct enrollment regulatory provisions have likewise been divided into sections separately applicable to QHP issuers participating in direct enrollment and web-brokers. As direct enrollment has evolved with the implementation of enhanced direct enrollment, many of the requirements applicable to QHP issuers performing direct enrollment and web-brokers have become increasingly similar. Therefore, we proposed to revise § 155.221 to apply to all types of direct enrollment entities and to expand the requirements captured in this regulation beyond audits of direct enrollment entities. To reflect this change we also proposed to revise the section heading of § 155.221 to “Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.”

As detailed above, we also proposed to amend § 155.20 to include definitions of several terms we proposed to use in § 155.221 including: “direct enrollment entity” and “web-broker.” Specifically, we proposed to define “direct enrollment entity” as an entity that an Exchange permits to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner considered to be through the Exchange as authorized by §§ 155.220(c)(3), 155.221, or 156.1230. We proposed to define “web-broker” as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in §§ 155.220(c)(3) and 155.221. As explained elsewhere in this preamble, we also proposed to define the term “web-broker” to include direct enrollment technology providers. We explained that it is important to distinguish “web-brokers” from other agents and brokers utilizing a non-Exchange website to assist consumers with direct enrollment in QHPs offered through the Exchanges when they did not develop and do not host the non-Exchange website. Stated differently, agents and brokers using a non-Exchange website developed and hosted by a web-broker are not themselves necessarily web-brokers. For the reasons outlined in the preamble to § 155.220, we are of the view that it is appropriate to impose different requirements on web-brokers and agents and brokers who are not web-brokers. The proposed definition and the proposed changes to §§ 155.220 and 155.221 reflect this approach and would enable web-brokers, agents, and brokers to more clearly identify when requirements are applicable to only web-brokers.

We also proposed to amend § 155.20 to define “direct enrollment technology provider” as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker to provide technology services to facilitate participation in direct enrollment as a web-broker in accordance with §§ 155.220(c)(3) and 155.221. This definition captures instances when an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, engages the services of or creates a technology company that is not licensed as an agent, broker, or producer to assist with the development

and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. When the technology company is not itself licensed as an insurance agency or brokerage, but otherwise is functioning as a web-broker, we proposed that these technology companies would be considered a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless indicated otherwise.¹³⁴ The proposed definition of “web-broker” reflects the inclusion of direct enrollment technology providers. As detailed above, we are finalizing these definitions as proposed. Please refer to the preamble for § 155.20 for a summary of comments on the proposed definitions.

We proposed to generally maintain the current requirements in § 155.221 that describe the standards for third-parties to perform audits of direct enrollment entities. However, to accommodate new content we proposed to add to this regulation, we proposed to redesignate the existing paragraphs (a) through (c) as paragraphs (e) through (g), respectively.

We also proposed some amendments to existing requirements currently captured in paragraphs (a) through (c), as described more fully below. In addition, throughout the redesignated paragraphs (e), (f), (f)(2), (f)(3), (f)(4), (f)(6), (f)(7), and (g), we proposed conforming edits to change references to agents, brokers, and issuers to direct enrollment entities. We also proposed to update the regulatory cross-references in the redesignated paragraph (f)(6) and (f)(7) from § 155.221(a) to § 155.221(e) to align with other proposed streamlining changes to this regulation. We also proposed to add paragraph headings throughout this revised regulation for further clarity. In paragraph (e), we also proposed to add language to require that the third-party entities that conduct annual reviews of direct enrollment entities to demonstrate operational readiness consistent with new § 155.221(b)(4)¹³⁵ be independent of the entities they are auditing. We proposed this change because we believe an independent audit is less likely to be

¹³⁴ For example, amendments to § 155.220(d)(2) exempt direct enrollment technology providers from the training requirement that is part of the annual FFE registration process for agents and brokers.

¹³⁵ Direct enrollment operational readiness review requirements are currently captured at § 155.220(c)(3)(i)(K) for web-brokers and § 156.1230(b)(2) for QHP issuers.

influenced by a direct enrollment entity’s business considerations and therefore is more reliable. We note that current § 155.221(b)(4) requires third-party auditors to disclose to HHS any financial relationships they have with the entities they are auditing. We explained in the proposed rule that we believe this disclosure requirement remains relevant even with the proposed addition to proposed paragraph (e) that will require auditors to be independent, because an auditor may be independent while also contracting with the entity it is auditing (and therefore having a financial relationship with the entity) to perform audits or other activities unrelated to those described in § 155.221. We therefore proposed to retain this disclosure requirement at new § 155.221(f)(4).

We also proposed to clarify in paragraph (e) that an initial audit is required, in addition to subsequent annual audits, and that these audits must include review of the entity’s compliance with applicable direct enrollment requirements. These clarifications do not represent a change from the current approach, as direct enrollment entities are currently required to demonstrate operational readiness before their websites may be used to complete QHP selections,¹³⁶ and these audits must confirm compliance with applicable requirements.¹³⁷ In paragraph (e), we proposed to add language to clarify that operational readiness must be demonstrated prior to the direct enrollment entity’s website being used to complete an Exchange eligibility application or make a QHP selection. This language is consistent with the operational readiness review requirements currently captured at § 155.220(c)(3)(i)(K) for web-brokers and § 156.1230(b)(2) for QHP issuers, which we proposed be moved to § 155.221(b)(4), and accounts for the fact that direct enrollment entities participating in enhanced direct enrollment will host the eligibility application in addition to QHP selection.

We proposed to maintain the last sentence that currently appears in § 155.221(a) as the last sentence of the new paragraph (e) that states the third-party entity will be the downstream or delegated entity of the agent, broker, or issuer that participates or wishes to participate in direct enrollment, replacing the references to agent, broker,

¹³⁶ See § 156.1230(b)(2) for issuers participating in direct enrollment and § 155.220(c)(3)(i)(K) for web-brokers.

¹³⁷ See § 155.221(b)(5). Also see § 156.1230(b)(2).

and issuer with direct enrollment entity. In paragraph (f), we proposed to generally maintain the current requirement captured in § 155.221(b) that a direct enrollment entity must satisfy the requirement to demonstrate operational readiness by engaging a third-party entity that complies with the specified requirements.

We also proposed to require under new paragraph (f) that a written agreement must be executed between the direct enrollment entity and its auditor stating that the auditor will comply with the standards outlined in paragraph (f). We proposed this new requirement because we believe the most effective way to ensure a direct enrollment entity has the necessary control and oversight over its auditor to ensure compliance with the applicable standards in § 155.221 is for those standards to be memorialized in a written agreement between the parties. We proposed to delete the provision in current paragraph (c) that refers to each third-party entity having to satisfy the standards outlined in current paragraph (b), to avoid duplication with a nearly identical provision in proposed paragraph (f).

We proposed to maintain, in the redesignated new paragraph (g), the provision that clarifies that direct enrollment entities may engage multiple third-party entities to conduct the operational readiness audits under proposed § 155.221(e).

We proposed a new paragraph (a) in § 155.221 that will establish the types of entities the FFEs will permit to assist consumers with direct enrollment in QHPs offered through an Exchange in a manner that is considered to be through the Exchange, to the extent permitted by state law. We proposed to capture in § 155.221(a) the two types of entities that are already permitted by the FFEs to use and offer a non-Exchange website to facilitate direct enrollment: QHP issuers that meet the requirements in § 156.1230 and web-brokers that meet the requirements in § 155.220. New proposed paragraph (a) also reflected that these entities would be required to comply with the applicable requirements outlined in the new proposed § 155.221, which we proposed to capture the direct enrollment requirements that would apply to both web-brokers and QHP issuers participating in direct enrollment. For the remaining requirements that only apply to web-brokers or only apply to QHP issuers participating in direct enrollment, we proposed to retain those requirements in §§ 155.220 and 156.1230, respectively.

In the proposed rule, we described guidance that details several existing display standards applicable to issuers or web-brokers participating in direct enrollment.¹³⁸

We explained that we received feedback from issuers and web-brokers suggesting there was some confusion about the current standards and guidance related to the display of QHPs and non-QHPs on non-Exchange websites used to facilitate direct enrollment. In an effort to clarify expectations, achieve greater uniformity in standards for all direct enrollment entities, and provide flexibility for innovation, we proposed to establish requirements under § 155.221(b) for the FFEs, which would apply to all FFE direct enrollment entities. As noted elsewhere in preamble, some of the proposed requirements in § 155.221(b) were intended to streamline existing web-broker and QHP issuer direct enrollment requirements that are currently separately imposed under §§ 155.220 and 156.1230 by capturing these similar requirements in one regulation. Other proposed standards in § 155.221(b) are new regulatory requirements and are proposed to clarify or otherwise address compliance questions that have arisen under the existing regulations and guidance.

At new § 155.221(b)(1), we proposed to require direct enrollment entities to display and market QHPs and non-QHPs on separate website pages on their respective non-Exchange websites. We explained that this proposal was intended to balance the goals of minimizing consumer confusion about distinct products with substantially different characteristics, and allowing marketing flexibility and opportunities for innovation. At § 155.221(b)(2), we proposed to require direct enrollment entities to prominently display a standardized disclaimer in the form and manner provided by HHS.¹³⁹ Consistent with current practice for the other standardized disclaimers provided by HHS under §§ 155.220 and 156.1230, we explained we would provide further

¹³⁸ See, for example, section 4.3 of the Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual, available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollment-Manual-062618.pdf>. Also see, section II.B of the Guidance for Web-brokers Registered with the Federally-Facilitated Marketplaces (October 17, 2016), available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-Web-brokers-FFMs.pdf>.

¹³⁹ As proposed, this new standardized disclaimer would be in addition to the existing requirements at § 155.220(c)(3)(i)(A) and (G) for web-brokers and at § 156.1230(a)(1)(iv) for QHP issuers participating in direct enrollment.

details on the text and other display details for the standardized disclaimer in guidance, but noted its purpose would be to assist consumers in distinguishing between direct enrollment entity website pages that display QHPs and those that display non-QHPs, and for which products APTC and CSRs are available, during a single shopping experience. In new § 155.221(b)(3), HHS proposed that direct enrollment entities must limit the marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that will minimize the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. For example, under the proposed display standards captured at § 155.221(b)(1) through (b)(3), direct enrollment entities would be required to offer an Exchange eligibility application and QHP selection process that is free from advertisements or information for non-QHPs and sponsored links promoting health insurance-related products. However, it would be permissible for a direct enrollment entity to market or display non-QHP health plans and other off-Exchange products in a section of the entity's website that is separate from the QHP web pages if the entity otherwise complied with the proposed standardized disclaimer requirements. The proposed requirements captured at § 155.221(b)(1)–(3) are intended to provide flexibility for direct enrollment entities to market valuable additional coverage that complements QHP coverage, while also allowing HHS to establish important parameters around the manner and type of non-QHPs that direct enrollment entities may market as part of a single shopping experience with QHPs. We explained that we believe marketing some products in conjunction with QHPs may cause consumer confusion, especially as it relates to the availability of financial assistance for QHPs purchased through the Exchanges. But we also appreciate that having flexibility to update these standards would allow us to adapt the display guidance as new products come to market and as technologies evolve that can assist with differentiating between QHPs offered through the Exchange and other products consumers may be interested in. We also noted our belief that the convenience of being able to purchase additional products as part of a single shopping experience outweighs potential consumer confusion, if proper safeguards can be put in place. In § 155.221(b)(4), we

proposed to move and consolidate the parallel requirements currently captured in §§ 155.220(c)(3)(i)(K) and 156.1230(b)(2) that web-brokers and QHP issuers, respectively, demonstrate operational readiness and compliance with applicable requirements prior to their internet websites being used to complete a QHP selection. We also included language in proposed § 155.221(b)(4) to clarify that operational readiness and compliance with applicable requirements must also be demonstrated prior to their internet websites being used to complete an Exchange eligibility application. We explained that this clarification was important as enhanced direct enrollment is implemented and approved direct enrollment entities are hosting the Exchange eligibility application on their non-Exchange websites. We proposed accompanying amendments to remove the operational readiness requirements from §§ 155.220 and 156.1230 as part of our efforts to streamline the regulatory requirements applicable to direct enrollment entities. Lastly, in § 155.221(b)(5), we proposed to capture the requirement for direct enrollment entities to comply with all applicable federal and state requirements. This would include the additional Exchange requirements in §§ 155.220 and 156.1230 that apply to web-brokers and QHP issuers that participate in direct enrollment, respectively.

In § 155.221(c), we proposed FFE requirements related to direct enrollment entity application assisters. Please see the preamble to § 155.415 for further details.

In § 155.221(d), we proposed to consolidate and amend the existing parallel provisions in §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) to authorize HHS to immediately suspend the direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations or Exchange information technology systems until such circumstances are resolved, remedied or sufficiently mitigated to HHS' satisfaction. We proposed to remove the provisions from §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) as part of our efforts to streamline and consolidate the requirements applicable to direct enrollment entities in one regulation. The proposal captured in § 155.221(d) includes language that will extend the authority to suspend the ability to transact information with the Exchange to also include discovery of

circumstances by HHS that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations. This addition was necessary and appropriate as enhanced direct enrollment allows direct enrollment entities to collect and transmit the application data that the Exchanges use to complete eligibility determinations.

Lastly, to account for direct enrollment entities that may be assisting consumers in SBE-FP states, we proposed a new § 155.221(h) to clarify that such entities are also required to comply with applicable standards in § 155.221.

We sought comment on all of these proposals. After consideration of the comments received, we are finalizing all of the amendments to § 155.221, as proposed.

Comment: We received numerous comments on the proposals at §§ 155.221(b)(1) and (3) to respectively require that QHPs and non-QHPs be displayed and marketed on separate website pages of non-Exchange websites and to limit marketing of non-QHPs during the Exchange application and QHP selection process. Many commenters supported the proposal to require QHPs and non-QHPs be displayed and marketed on separate website pages on non-Exchange websites. Some commenters were opposed to any marketing of non-QHPs, even after the Exchange application and QHP selection process, on non-Exchange websites. One commenter stated that allowing this type of marketing creates incentives for brokers to advise consumers to spend more money on supplemental plans and less on QHPs, which the commenter was concerned would not be in the consumer's interest. Some commenters specifically cited concerns about the marketing of short-term, limited-duration insurance plans. Some commenters recommended we adopt requirements that help consumers understand the differences between QHPs and non-QHPs, and the availability of financial assistance only applying to QHPs. One commenter agreed with the goal of the proposal to minimize consumer confusion, but was opposed to limiting the marketing of non-QHP products until after the Exchange application and QHP selection processes are complete, and claimed this limitation would suppress web-broker participation. One commenter was opposed to most limits on marketing non-QHPs, and wanted web-brokers to be able to display and market non-QHP alternatives to QHPs, rather than just complementary non-

QHP products during the consumer's shopping experience.

Response: We are finalizing the amendments to create new § 155.221(b)(1) and (3) as proposed. As explained in the proposed rule, we have consistently received feedback from QHP issuers and web-brokers about confusion with respect to the current guidance and standards related to the display and marketing of QHPs and non-QHPs on their respective non-Exchange websites. We believe this approach provides additional clarity and represents a balance that minimizes the chance that consumers will be confused about the products being offered to them, including which products APTC and CSRs are available for, while also allowing some marketing of complementary non-QHP products after the Exchange application and QHP selection is complete but during a single shopping experience on non-Exchange websites. This provision will not limit web-brokers or issuers from marketing non-QHP products to consumers outside the Exchange application and QHP selection processes, but if a consumer has decided to complete the Exchange eligibility application or to shop for QHPs on a non-Exchange website, we believe the marketing of non-QHP products to them during that time would cause confusion about which products are offered through the Exchange (and therefore subject to applicable requirements and eligible for APTC and CSRs) and which are not. The disclaimer requirement established at § 155.221(b)(2) is intended to help consumers understand the difference between QHPs and non-QHPs, and that financial assistance is only available for QHPs. We do not believe this policy creates new incentives for brokers to market non-QHP products instead of QHPs. To the extent those incentives exist, they exist with or without this policy. Similarly, we do not believe this policy has any implications specific to the marketing of short-term, limited-duration insurance plans generally. Under § 155.221(b)(1) it is not permissible to display or market any non-QHP plans, including short-term, limited-duration insurance plans, on the same website pages as QHPs.

As described in the proposed rule and above, the requirements at § 155.221(b)(1) through (3) are intended to provide flexibility for direct enrollment entities to market valuable additional coverage that complements QHP coverage, while also allowing HHS to establish important parameters around the manner and type of non-QHPs that direct enrollment entities may market as part of a single shopping

experience with QHPs offered through the Exchange. We may release additional guidance, as may be necessary or appropriate, to further clarify the new standards we are finalizing at § 155.221(b)(1) through (3) for direct enrollment entities that wish to display and market non-QHPs on separate web pages but as part of a single shopping experience with QHPs offered through the Exchange.

f. Certified Application Counselors (§ 155.225)

We proposed allowing, but not requiring, certified application counselors to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker websites under certain circumstances. We are not finalizing this proposal. For a discussion of the provisions of this final rule related to that proposal, please see the preamble to § 155.220.

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

a. Allowing Issuer Application Assistants To Assist With Eligibility Applications (§ 155.415)

In the first Program Integrity Rule,¹⁴⁰ we finalized § 155.415, which allows an Exchange, to the extent permitted by state law, to permit issuer application assistants to assist consumers in the individual market with an Exchange eligibility application if they met certain requirements. At § 155.20, we define issuer application assister as an employee, contractor, or agent of a QHP issuer who is not licensed as an agent, broker, or producer under state law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs. At current § 156.1230(a)(2), when permitted by an Exchange under § 155.415, and to the extent permitted by state law, QHP issuers that elect to use application assistants are required to ensure that each of their application assistants at least: (1) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules; (2) complies with the Exchange privacy and security standards consistent with § 155.260; and (3) complies with applicable state law related to the sale, solicitation, and negotiation of health insurance

products, including laws related to agent, broker, and producer licensure, confidentiality, and conflicts of interest.

In adopting this approach, we recognized that, in some states, a license may be required to assist an applicant applying for an eligibility determination or redetermination. We deferred to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees as authorized under § 156.1230(a)(2), and whether licensure would be required to provide such assistance. We stated that if state law requires a license to enroll applicants in coverage, then issuers and their application assistants would need to follow state law for licensure requirements. We also recognized that there were certain functions that issuers generally had their staff perform prior to the issuance of the first Program Integrity Rule, such as answering general information about plans, and we wanted to allow those individuals to continue to perform those functions, without meeting additional standards, if permitted by state law. We indicated that, if an issuer wants those individuals to perform additional functions, such as helping consumers as they apply for an eligibility determination or redetermination for coverage through the Exchange, or as they apply for insurance affordability programs, or as they report changes to an Exchange, those individuals could assist consumers with applications subject to the standards in § 156.1230(a)(2), so long as providing such assistance did not otherwise conflict with state law. Additionally, we stated that facilitating selection of a QHP may be a typical function of issuer staff and issuer staff will be able to perform post-eligibility functions such as plan compare and selection, if permitted by state law, without being subject to the standards of § 156.1230(a)(2). As currently codified, the application assister definition and accompanying requirements only apply to issuer application assistants.

As described in the proposed rule, we believe providing parity for direct enrollment entities, when possible, promotes fair competition and maximizes consumer choice. In addition, there was no apparent reason why issuer staff are more qualified to assist consumers with the Exchange eligibility application than the staff of other direct enrollment entities, assuming all receive appropriate training and when otherwise permitted under applicable state law. Therefore, we proposed to expand the flexibility to employ or contract with application assistants to all direct enrollment entities,

to create parity between issuers and other types of direct enrollment entities. Accordingly, we proposed changes to several regulatory sections. Specifically, we proposed to amend § 155.20 by adding the term “direct enrollment entity application assister,” which we proposed to define as an employee, contractor, or agent of a direct enrollment entity who is not licensed as an agent, broker, or producer under state law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs. We proposed to adopt the same approach for direct enrollment entity application assistants as the existing one for issuer application assistants. In other words, under our proposal, these application assistants would need to comply with applicable state law, including any licensure requirements, and we would continue to defer to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees and whether licensure is required to provide such assistance.

We also proposed to revise § 155.415(a) to authorize an Exchange, to the extent permitted by state law, to permit issuer and direct enrollment entity application assistants, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and insurance affordability programs. Additionally, we proposed to maintain language in § 155.415(a) to mandate that all direct enrollment entities who seek to use application assistants, and not just QHP issuers, must ensure that their application assistants meet the standards currently captured in § 156.1230(a)(2), which we proposed to move to new paragraphs (b)(1) through (3) of § 155.415, with two proposed amendments. Currently, § 156.1230(a)(2)(i) requires all QHP issuer application assistants to receive training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations. In the proposed rule, we noted that licensed agents and brokers currently assisting consumers with QHP enrollment through the FFEs and SBE-FPs must have credentials to access FFE systems to offer that assistance. Those credentials are obtained during the FFE registration and training processes for agents and brokers. For application assistants to have similar access to FFE systems, so that they are also able to assist consumers as described in this

¹⁴⁰ Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54070 (August 30, 2013).

rule, they will need credentials similar to those obtained by agents and brokers during the FFE registration and training processes. Therefore, we proposed to require that application assisters providing assistance in the FFEs and SBE-FPs complete a similar annual registration and training process as to what is required for agents and brokers under § 155.220(d)(1) and (2), in a form and manner to be specified by HHS, so that they will have the necessary training before being provided credentials to assist consumers and access FFE systems. This proposed new training and registration requirement for application assisters is captured in the new proposed § 155.415(b)(1). Currently, § 156.1230(a)(2)(iii) requires all QHP issuer application assisters to comply with applicable agent, broker, and producer licensure laws, which may not be applicable in a given circumstance. For example, another state licensure law may exist for professionals whose functions are more similar to application assisters than licensed agents, brokers, and producers. We, therefore, proposed to amend this standard (proposed to be redesignated at § 155.415(b)(3)) to require all application assisters to comply with applicable state law related to the sale, solicitation and negotiation of health insurance products, including any state licensure laws applicable to the functions to be performed by the application assister; confidentiality; and conflicts of interest. We did not propose any changes to the other standard for application assisters that requires compliance with the Exchange's privacy and security standards adopted consistent with § 155.260 (proposed to be redesignated from § 156.1230(a)(2)(ii) to new § 155.415(b)(2)). We also proposed to delete and reserve § 156.1230(a)(2) to reduce redundancies, as QHP issuers subject to the current standards captured at § 156.1230(a)(2) would be subject to the requirements in § 155.415(b) if they elect to use application assisters. We note that any QHP issuers that are not direct enrollment entities, but use application assisters, will also be subject to these requirements and able to use application assisters, to the extent permitted by the applicable Exchange and state law. Finally, consistent with the new paragraphs at § 155.221(c) and (h), we clarified that direct enrollment entities participating in FFEs or SBE-FPs will be permitted to use application assisters, to the extent permitted by state law.

We sought comment on these proposed changes. We are finalizing

these amendments as proposed, with technical edits to § 155.415(b)(3) to clarify that the reference at the end of the subparagraph to "confidentiality and conflicts of interest" is referring to such standards as are imposed under State law. We further note that HHS will permit application assisters to perform the assistance functions outlined in § 155.415 to assist consumers using the FFEs and SBE-FPs, to the extent allowed under state law, beginning with the 2021 open enrollment period. HHS needs additional time to implement the registration and training processes necessary to operationalize this proposal while maintaining safeguards to protect consumer data and Exchange systems. SBEs that do not rely on the federal platform can implement these provisions sooner, to the extent otherwise permitted under state law. We intend to release future guidance about the form and manner of the registration and training processes under § 155.415(b)(1) for application assisters participating in the FFEs or SBE-FPs.

Comment: Two commenters supported this proposal. Two other commenters questioned whether direct enrollment entity application assisters would be subject to state laws applicable to licensed agents or brokers, such as those pertaining to protecting consumer information, conflicts of interest, and professional liability insurance. Two commenters also suggested direct enrollment entity application assisters should be subject to requirements similar to those for agents or brokers under § 155.220.

Response: We are finalizing this proposal as proposed, with a clarifying edit to § 155.415(b)(3) to clarify that the reference at the end of the subparagraph to "confidentiality and conflicts of interest" is referring to such standards as are imposed under state law. We understand that in some states a license may be required for application assisters to assist consumers applying for an eligibility determination or redetermination. We defer to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees as described in this rule, and whether state licensure is required to provide such assistance. If state law requires a license to engage in these activities, then application assisters will need to follow state law for licensure requirements. Since application assisters under the federal definition are not licensed agents or brokers, we do not believe it is appropriate to subject them to the same requirements imposed on licensed agents and brokers under § 155.220. Notably, application assisters

are not authorized to function in the same ways as licensed agents or brokers. However, there are some requirements finalized in this rule applicable to application assisters that are similar to those applicable to agents or brokers assisting consumers in the FFEs and SBE-FPs, including requirements to comply with Exchange privacy and security standards. In addition, as described above, application assisters in the FFEs and SBE-FPs will be required to complete registration and training similar to agents or brokers who participate in Exchanges. We will release future guidance about the form and manner for the registration and training processes for application assisters who wish to participate in FFEs and SBE-FPs. Also, as finalized in this rule at § 155.415(b)(3), all application assisters must comply with applicable state law related to the sale, solicitation and negotiation of health insurance products, including any state licensure laws applicable to the functions to be performed by the application assister, as well as applicable state law related to confidentiality and conflicts of interest.

b. Special Enrollment Periods (§ 155.420)

Under our current rules, individuals who are enrolled in employer-sponsored coverage or coverage purchased through an Exchange are eligible for a special enrollment period if they become newly eligible for APTC. However, no comparable special enrollment period exists for individuals who are enrolled in off-Exchange individual market coverage. We believe this may present a significant barrier for some individuals to remain in continuous coverage for the full plan year. Therefore, we proposed to amend § 155.420(d) to add new paragraph (d)(6)(v) to authorize Exchanges, at their option, to provide a special enrollment period to enroll in Exchange coverage for off-Exchange individual market enrollees who experience a decrease in household income and receive a new determination of eligibility for APTC by an Exchange. We proposed to make this special enrollment period available to qualified individuals and their dependents who experience circumstances that result in a decrease in household income if the qualified individual or his or her dependent are both (1) newly determined eligible for APTC by an Exchange, and (2) had MEC in which they were enrolled in and entitled to receive benefits as described in 26 CFR 1.5000A-1(b) for one or more days during the 60 days preceding the change in circumstances. We cite 26

CFR 1.5000A–1(b) because it sets forth criteria for what it means to “have MEC,” including general requirements to be enrolled in and entitled to receive benefits under a program or plan identified as MEC under 26 CFR 1.5000A–2 and certain situations under which an individual is not enrolled in MEC but is treated as “having MEC.” Under this special enrollment period, qualified individuals and dependents will be eligible for Exchange coverage following the regular prospective coverage effective date rules described in paragraph (b)(1) of this section, and must enroll within 60 days from the date of the financial change, in accordance with paragraph (c)(1) of this section.

We sought to provide individuals with more health coverage options and to empower them to enroll in the health coverage that best meets their needs and the needs of their families. For individuals and families with household incomes greater than 400 percent of the federal poverty level (FPL) who are not eligible for APTC, this may mean that they choose to purchase health insurance coverage outside of the Exchange during the annual open enrollment period or another eligible enrollment period, especially if the market outside of the Exchange offers additional plan options at more affordable prices. However, these individuals or families may experience a change in household income during the benefit year that makes their current health coverage no longer affordable. While paragraphs (d)(6)(iii) and (d)(6)(iv) currently provide special enrollment periods for individuals whose employer-sponsored coverage becomes unaffordable or does not provide minimum value, resulting in the employee becoming newly eligible for APTC, and for individuals previously in the coverage gap who become newly eligible for APTC as a result of a change in household income or move, respectively, there is no current pathway to Exchange coverage for enrollees in off-Exchange individual market plans who are newly eligible for APTC. Since no pathway to Exchange coverage currently exists, we believe that unsubsidized individual market enrollees whose household income has decreased may no longer be able to afford their unsubsidized health plans and may decide to terminate coverage mid-year. Therefore, the special enrollment period in paragraph (d)(6)(v) will address this issue by establishing a pathway to Exchange coverage for qualified individuals enrolled in off-Exchange coverage who experience a

decrease in household income and are newly determined eligible for APTC. We believe that this policy will help promote continuous enrollment in health coverage and bring additional stability to the individual market risk pool, which will likely have a positive impact on health insurance premiums.

Individuals seeking to access the special enrollment period will not be current Exchange enrollees and will receive a new determination of eligibility for APTC through the Exchange’s consumer application. For the FFEs, an individual’s current household income and eligibility for APTC will be verified through the FFE’s eligibility system and data matching issue resolution process, in accordance with the requirements in § 155.320(c). To ensure that the special enrollment period is available to the intended population while mitigating risks of adverse selection and inappropriate use, we proposed to require the individual seeking access to the special enrollment period to provide evidence of both a change in household income and of prior health coverage. Verifying that a decrease in household income occurred will prevent individuals who enrolled in health coverage off-Exchange, but have not experienced a financial change, from attempting to use this special enrollment period for the sole purpose of purchasing a more or less comprehensive level of coverage mid-year. To protect the individual market risk pool from adverse selection, as mentioned in this rule, we proposed to include a prior coverage requirement, which will protect against individuals who opted not to enroll in health coverage during the annual open enrollment period from using this special enrollment period to enroll in Exchange coverage mid-year. Additionally, this prior coverage requirement will promote continuous coverage. The prior-coverage requirement aligns with existing prior-coverage requirements for special enrollment periods at § 155.420(d)(2)(i) and (d)(7). We envision leveraging existing pre-enrollment verification procedures¹⁴¹ to confirm eligibility for the special enrollment period, either through review of an individual’s submitted documentation or through use of electronic data sources, when available, prior to sending the individual’s plan selection to the issuer for enrollment. Consistent with current

¹⁴¹ Instructions for consumers to verify their eligibility for a special enrollment period are available at <https://www.healthcare.gov/coverage-outside-open-enrollment/confirm-special-enrollment-period/>.

practices, in cases where eligibility is not verified electronically, individuals will be required to submit documentation within 30 days of plan selection to verify their prior coverage and their decrease in income. Consumer-submitted documents currently accepted by the FFE for purposes of demonstrating prior coverage and verifying attested income are currently identified on HealthCare.gov,¹⁴² and we anticipate developing additional consumer instructions relating to submitting documents to verify a decrease in income.

We recognize that State Exchanges maintain flexibility to determine whether and how to implement pre-enrollment verification of eligibility for special enrollment periods and may not have the operational capacity to immediately implement and verify eligibility for this special enrollment period. Some State Exchanges may also determine there is insufficient need among off-Exchange consumers for this special enrollment period because of the rating and pricing practices specific to their state markets. Therefore, we proposed to make this special enrollment period available at the option of the Exchange.

This special enrollment period is intended only for individuals not currently enrolled in Exchange coverage, since current Exchange enrollees who experience a decrease in household income mid-year may already qualify for a special enrollment period under paragraphs (d)(6)(i) and (ii), or may enroll in off-Exchange plans if they become newly ineligible for APTC under § 147.104(b)(2)(i)(B).

Paragraph (a)(4)(iii) of § 155.420 generally limits the plans into which an enrollee who qualifies for a special enrollment period or is adding a dependent through a special enrollment period may enroll. Several special enrollment periods are excluded from this limitation. However, we proposed that the new special enrollment period will be subject to the rule in paragraph (a)(4)(iii). Therefore, should a qualified individual who qualifies for the special enrollment period in paragraph (d)(6)(v) already have members of his or her household enrolled in Exchange coverage and those enrollees do not qualify for another special enrollment period at the same time that provides them with additional plan enrollment flexibilities, the Exchange must allow

¹⁴² Available at <https://www.healthcare.gov/help/prove-coverage-loss/> and <https://www.healthcare.gov/verify-information/documents-and-deadlines/>.

the qualified individual to be added to the same QHP as the Exchange enrollees in his or her household, if the plan business rules allow. If the plan's business rules do not allow the qualified individual to enroll, the Exchange must allow the current enrollees to change to another QHP within the same level of coverage (or one metal level higher or lower if no such QHP is available), and to add the qualified individual to the same plan as outlined under § 156.140(b). As always, and at the option of the qualified individual, he or she may enroll in a separate QHP at any metal level, in accordance with § 155.420(a)(4)(iii)(B). We anticipate that this situation will arise relatively infrequently due to the availability of the special enrollment periods at (d)(6)(i) and (d)(6)(ii) of § 155.420 for enrollees who become newly eligible for APTC or experience a change in eligibility for cost-sharing reductions.

We also proposed to modify the types of coverage that may satisfy the prior coverage requirement by amending § 155.420(a)(5) to include the coverage types described in paragraphs (d)(1)(iii) and (iv) of this section, such as pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, in addition to MEC described in 26 CFR 1.5000A-1(b). We believe that this clarification is necessary to ensure consistency across our special enrollment period regulations for the types of coverage that qualify an individual for a special enrollment period. We already treat certain types of coverage, including pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, although not independently designated as MEC under 26 CFR 1.5000A-1(b), as MEC for purposes of qualifying for the loss of MEC special enrollment period described in § 155.420(d)(1). However, individuals currently enrolled in these types of coverage will not qualify for special enrollment periods that require prior coverage. To avoid treating the same types of coverage differently for purposes of eligibility for different special enrollment periods, we proposed an aligning edit to paragraph (a)(5).

Lastly, we proposed to clarify certain terms in § 155.420(b)(2)(iv), which addresses the coverage effective dates that apply to the special enrollment periods in § 155.420(d)(1), (d)(3), (d)(6)(iii), (d)(6)(iv), and (d)(7). Specifically, we proposed to replace the word "consumer" with the phrase "qualified individual, enrollee, or dependent, as applicable," to align with the terminology used at § 155.420(d) to describe special enrollment period

triggering events. We do not anticipate that this wording change will create additional cost or burden for Exchanges or for any other stakeholders.

Comment: We received broad support from commenters for the proposals at § 155.420. Commenters noted the proposed special enrollment period creates consistency with existing special enrollment periods available to individuals who are enrolled in employer-sponsored coverage or coverage purchased through an Exchange who become newly eligible for APTC. Commenters noted the proposed special enrollment period would promote continuous coverage among consumers and increase access to care. We also received comments in support of the modification to prior coverage requirements at § 155.420(a)(5) to include coverage types such as pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, in addition to MEC described in 26 CFR 1.5000A-1(b).

Response: We are finalizing all policies under § 155.420 as proposed. We note that the proposed new special enrollment period under § 155.420(d)(6)(v) is available at the option of the Exchange. HHS is determining the date on which this special enrollment period will be implemented for Federally-facilitated Exchanges and State Exchanges using the federal eligibility and enrollment platform, and anticipates it will not be available until after January 1, 2020.

Comment: One commenter expressed support for the proposed new special enrollment period under § 155.420(d)(6)(v), but urged HHS to reduce the overall number of special enrollment periods to align with the private market and Medicare Advantage program.

Response: HHS is committed to making sure special enrollment periods are available to those who are eligible for them, and equally committed to avoiding any misuse or abuse of special enrollment periods. Recently implemented special enrollment period policies, such as pre-enrollment verification and plan category limitations, are intended to promote continuous enrollment in coverage and protect the risk pool from adverse selection that may have a destabilizing impact on the market for existing enrollees. Given these mitigation strategies, we do not believe it is necessary to reduce the number of available special enrollment periods under § 155.420 at this time.

Comment: Several commenters wrote in support of the proposed requirement that the special enrollment period under

proposed § 155.420(d)(6)(v) be available to consumers who were previously enrolled in MEC as defined at 26 CFR 1.5000A-1(b). These commenters wrote that continuous enrollment in comprehensive coverage is important to maintaining a stable risk pool, and expressed concern about adverse selection should the special enrollment period be made available to consumers enrolled in alternate types of coverage such as short-term, limited-duration insurance or health care sharing ministry plans.

Response: We agree that the proposed prior coverage requirement is important to promote continuous coverage and protect against adverse selection, and note that MEC described in 26 CFR 1.5000A-1(b) excludes the coverage types of primary concern to commenters.

Comment: Other commenters stated short-term, limited-duration insurance and other coverage types not currently designated as MEC should be considered to meet the prior coverage requirements for the proposed special enrollment period. Some commenters referenced HHS support for these coverage options in other rulemaking and guidance, and other commenters expressed concern that consumers may be misled into unintentional enrollment into short-term, limited-duration plans.

Response: The Administration seeks to make more coverage options available to consumers, including short-term, limited-duration coverage and other forms of coverage that may not constitute MEC. However, the prior coverage requirements, as implemented in our other special enrollment periods, are intended to promote continuous coverage in MEC and protect the risk pool from adverse selection.

Comment: One commenter suggested we amend the proposed regulatory text to reference prior coverage requirements at § 155.420(a)(5) as opposed to 26 CFR 1.5000A-1(b) to enhance clarity of the prior coverage requirement.

Response: We believe this change, if implemented, would require additional aligning edits for all special enrollment periods containing a prior coverage requirement. We will consider this when making future technical amendments to regulations at § 155.420, but will not make such changes at this time.

Comment: Other commenters stated eligibility for the proposed special enrollment period under § 155.420(d)(6)(v) should be expanded to include consumers who were automatically re-enrolled in either subsidized or unsubsidized health plans which become unaffordable.

Response: Consumers in this scenario may be eligible for the special enrollment period as proposed, provided that they experience a decrease in income and that the plan in which they were automatically re-enrolled meets the current definition of MEC. Consumers automatically re-enrolled into Exchange coverage and who experience a change in eligibility for financial assistance outside the annual open enrollment period may also access the current special enrollment period at § 155.420(d)(6)(i) and (d)(6)(ii).

Comment: Another commenter questioned whether the proposed new special enrollment period under § 155.420(d)(6)(v) should be made available to consumers who experience a change in tax household composition or a resolution of a prior year tax return that causes an individual to become newly eligible for APTC in an Exchange plan.

Response: We believe that many consumers who experience in change in tax household composition may qualify for a special enrollment period under existing regulations, such as in cases of marriage and gaining or becoming a dependent. HHS offered a one-time special enrollment period to consumers who did not enroll in Exchange coverage because they failed to reconcile their APTC on their tax return during the first year of implementation of this requirement. However, we do not believe a permanent extension of this special enrollment period through this proposal is appropriate, as consumers now have multiple years of experience with the requirement that they must file a tax return and reconcile APTC to remain eligible for future APTC. For these reasons, we are finalizing the eligibility requirements for the special enrollment period as proposed and will not expand eligibility as suggested by the commenter.

Comment: Another commenter suggested that consumers should have 90 days, instead of 60 days, to report their financial change to the Exchange.

Response: We believe the current window of 60 days provides ample time for consumers to report triggering events to the Exchange and make authorized plan changes and, in many instances, encourages consumers to avoid extended lapses in health coverage. As a result, we will not increase the time within which consumers must report triggering events to qualify for a special enrollment period.

Comment: Several commenters expressed support for our proposal to require consumers to submit evidence to demonstrate they have experienced a decrease in household income and met

the prior coverage requirement. One commenter requested additional information on how these measures would protect against fraud.

Response: We agree that requiring evidence of prior coverage and a decrease in household income are important program integrity measures that protect against fraud. We believe these requirements provide sufficient mitigation against inappropriate use of the proposed special enrollment period.

Comment: Other commenters expressed concern regarding the consumer burden associated with verification requirements and requested more information on what types of consumer documents would be accepted. Another commenter stated that verifying a consumer's decrease in household income creates an undue burden, and that there is no evidence to support the notion that consumers will seek to switch plan category levels mid-year due to health status.

Response: We appreciate that the proposed verification requirements do require consumers to submit documents in most cases. However, our experience with pre-enrollment verification for special enrollment periods demonstrates that consumers are not significantly burdened by these requirements, as the vast majority of special enrollment period applicants who are required to submit documents to complete enrollment are able to successfully verify their eligibility. We maintain that the verification of a consumer's decrease in household income is an important program integrity measure to ensure individual consumers are not able to access this special enrollment period solely due to a change in health status, and are finalizing this verification requirement as proposed. To mitigate consumer burden, we intend to utilize electronic data sources where possible and will leverage existing processes to accept document types that are currently in use by HHS to verify prior coverage and income information.¹⁴³

Comment: Many commenters supported making the proposed special enrollment period at § 155.420(d)(6)(v) at the option of the Exchange. Other commenters urged HHS to require the special enrollment period for all Exchanges and questioned whether HHS would promote the new special enrollment period in its marketing and outreach materials.

¹⁴³ Consumer submitted documents currently accepted by the FFE for purposes of demonstrating prior coverage and verifying attested income are available at <https://www.healthcare.gov/help/prove-coverage-loss/> and <https://www.healthcare.gov/verify-information/documents-and-deadlines/>, respectively.

Response: We believe State Exchanges are well positioned to assess both the consumer need and the Exchange's operational capacity to implement the proposed special enrollment period and its verification requirements and we are finalizing the proposed special enrollment period at the option of the Exchange. Given the importance of pre-enrollment verification to protecting against adverse selection and misuse of the proposed special enrollment period, we believe requiring the special enrollment period to be implemented by State Exchanges which have not fully implemented pre-enrollment verification may inject adverse risk into the Exchange's marketplace. HHS intends to update current technical assistance and training materials to include information regarding the new special enrollment period and will provide information to relevant stakeholder groups such as issuers, agents and brokers, and consumer assisters.

Comment: Another commenter requested that State Exchanges who rely on the federal eligibility and enrollment platform be granted flexibility to choose to implement the special enrollment period.

Response: HHS intends to implement this special enrollment period for all Exchanges currently using the federal eligibility and enrollment platform, and currently lacks the operational capacity to offer this flexibility.

4. Eligibility Standards for Exemptions (§ 155.605)

a. Eligibility for an Exemption Through the IRS (§ 155.605(e))

Individuals can claim hardship exemptions through the tax filing process for hardships described in § 155.605(e)(1) through (4), which include most hardship exemptions, but not the general hardship types described in paragraph (d)(1) of this section. Allowing the general hardship exemption types to be claimed through the IRS will increase flexibility and decrease burdens for individuals seeking hardship exemptions. Therefore, we proposed to amend § 155.605(e), which describes the exemptions that can be claimed through the IRS tax filing process without an individual having to obtain an exemption certificate number from an Exchange, to add a new paragraph (e)(5) that will allow individuals to claim through the tax filing process hardship exemptions within all of the categories described in paragraph (d)(1) of this section on a federal income tax return

for tax year 2018 only. We are finalizing this change as proposed.

This rule aligns with HHS guidance published on September 12, 2018, entitled, “Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS)”¹⁴⁴ and with IRS Notice 2019–05.¹⁴⁵ We anticipate that the guidance and this rule will provide individuals with additional flexibility for claiming a hardship exemption by providing individuals the additional option of claiming this exemption on their federal income tax return for 2018 only.

Comment: Commenters generally supported the proposal for individuals to claim hardship exemptions on their tax returns without obtaining an exemption certification number from the Marketplace, because it will reduce burden on individuals.

Response: We are finalizing this change as proposed. We agree that this change will lessen the burden on individuals by allowing them to claim the general hardship exemptions through the tax filing process for tax year 2018. It will further reduce burden since individuals will not be required to obtain an exemption certification number from the Marketplace prior to filing their tax returns.

Comment: One commenter stated the proposal was unnecessary given that tax filing season for 2018 returns is underway (this change only applies to the 2018 tax year) and that HHS has not been transparent in the past about the specifications for claiming each type of hardship exemption.

Response: The PPACA grants authority to the Exchanges to grant all exemptions. As a result, HHS has consistently codified in regulations any grant of authority it has provided to the IRS in subregulatory guidance for specific hardship exemptions. And although tax filing season for the 2018 tax year has already begun, HHS plans to maintain our prior practice of providing regulatory revisions when granting authority to the IRS for individuals to claim specific exemptions through the tax filing process. In 2018, HHS published guidance allowing individuals to claim the general hardship exemptions through the IRS on their 2018 tax returns.¹⁴⁶ Also in 2018, we published guidance that provided examples of general hardships that an individual

may claim, such as single-issuer county hardships.¹⁴⁷ This guidance did not alter the existing regulations and did not create any new substantive requirements for people seeking a hardship exemption.

Comment: One commenter claimed the proposal undermines the original intent of Congress in enacting the individual mandate by making it too easy for individuals to claim a general hardship exemption.

Response: While we agree that the PPACA’s provisions incentivize consumers to obtain health insurance in many respects, the PPACA provides statutory authority for hardship exemptions. Consistent with its authority, HHS seeks to provide individuals with these exemptions in a manner that minimizes burden.

b. Required Contribution Percentage (§ 155.605(d)(2))

Under section 5000A of the Code, an individual must have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under § 155.605(d)(2), an individual is exempt from the requirement to have MEC if the amount that he or she will be required to pay for MEC (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her projected household income for a year. Although the Tax Cuts and Jobs Act reduces the individual shared responsibility payment to \$0 for months beginning after December 31, 2018, the required contribution percentage is still used to determine whether individuals above the age of 30 qualify for an affordability exemption that will enable them to enroll in catastrophic coverage under § 155.305(h).

The initial 2014 required contribution percentage under section 5000A of the Code was 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 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. The excess of the rate of premium growth over the rate of income growth is also 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 discussed elsewhere in this preamble, we proposed as the measure for premium growth a 2020 premium adjustment percentage of 1.2969721275 (or an increase of about 29.7 percent over the period from 2013 to 2019). We are finalizing the new premium growth measure that would be composed of individual market premium growth and employer-sponsored insurance premium growth. Therefore, as noted later in this preamble, we are finalizing a premium adjustment percentage of 1.2895211380 for the 2020 benefit year.¹⁴⁸ This amount reflects an increase of about 3.02 percent over the 2019 premium adjustment percentage (1.2895211380/1.2516634051).

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we will use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice, using the National Health Expenditure Account (NHEA) data, the rate of income growth for 2020 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year (\$56,261 for 2019) exceeds per capita PI for 2013 (\$44,922), carried out to ten significant digits. The ratio of per capita PI for 2019 over the per capita PI for 2013 is estimated to be 1.2524152976 (that is, per capita income growth of about 25 percent).¹⁴⁹ This reflects an increase of approximately 3.9 percent relative to the increase for 2013 to 2018 (1.2524152976/1.2059028167) used in the 2019 Payment Notice. Per capita PI includes government transfers, which refers to benefits individuals receive from federal, state, and local governments (for example, Social Security, Medicare, unemployment

¹⁴⁸ Note: As explained in the subsequent footnote, this amount differs from the proposed premium adjustment percentage due to the fact that we utilize the most recent NHEA data, which updated in February 2019.

¹⁴⁹ The 2013 and 2019 per capita personal income figures used for this calculation reflect the latest NHEA data, which was updated between the publication of the proposed rule and this final rule, on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS website, which can be accessed by clicking the “NHE Projections 2018–2027—Tables” link located in the Downloads section at the following address: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. A detailed description of the NHE projection methodology is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf>.

¹⁴⁴ <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf>.

¹⁴⁵ <https://www.irs.gov/pub/irs-drop/n-19-05.pdf>.

¹⁴⁶ <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf>.

¹⁴⁷ <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2018-Hardship-Exemption-Guidance.pdf>.

insurance, workers' compensation, etc.).¹⁵⁰

Using the 2020 premium adjustment percentage finalized in this final rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2019 is 1.2895211380/1.2524152976, or 1.0296274251. This results in a required contribution percentage of 8.00* 1.0296274251 or 8.24 percent for the 2020 benefit year, which when rounded to the nearest one-hundredth of one percent, represents a decrease of 0.07 of a percentage point from 2019 (8.23702–8.30358).

We also requested comment on whether we should exclude any government transfers (that is, Social Security, Medicare, unemployment insurance, workers' compensation, etc.) from per capita PI, but we did not receive any comments in response to this request.

Comment: Two commenters indicated that they oppose policies that reduce access to health coverage, including the proposed required contribution percentage increases resulting from the proposed change in premium adjustment percentage. Another commenter noted that the proposal would increase the number of individuals who are eligible for catastrophic coverage, which should be adequate to address a patient's needs and thereby not contribute to an expansion of short-term limited duration insurance plans.

Response: HHS is required to update the required contribution percentage annually for purposes of determining whether individuals above the age of 30 qualify for an affordability exemption that will enable them to enroll in catastrophic coverage under § 155.305(h). We note that as a result of the updated premium adjustment percentage finalized elsewhere in this rule, the required contribution percentage has decreased. For further discussion of the updated premium adjustment percentage for 2020, refer to section F(3)(e) of this preamble.

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

1. Definitions (§ 156.20)

We are defining the term “generic” in part 156 in response to comments requesting a definition related to the proposal that amounts paid toward cost

sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent not be required to be counted toward the annual limitation on cost sharing. For a discussion of that proposal and the related definition we are finalizing at § 156.20, please see the preamble to § 156.130.

2. FFE and SBE–FP User Fee Rates for the 2020 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. 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 annual 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 where enrollment is through an FFE or SBE–FP.

OMB Circular No. A–25R established federal policy regarding user fees; it specifies that a user fee charge will be assessed against each identifiable recipient of special benefits derived from federal activities beyond those received by the general public. 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. As in benefit years 2014 through 2019, issuers seeking to participate in an FFE in the 2020 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. For the 2020 benefit year, issuers participating in an FFE will receive special benefits from the following federal activities:

- 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).

Based on estimated costs, enrollment, and premiums for the 2020 benefit year, we proposed a 2020 benefit year user fee rate for all participating FFE issuers of 3.0 percent of total monthly premiums. This rate is lower than the 3.5 percent FFE user fee rate that we had established for benefit years 2014 through 2019. The lower user fee rate for the 2020 benefit year reflects our estimates of premium increases and enrollment decreases for the 2020 benefit year. We sought comment on this proposal.

As 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. SBE–FPs enter into a Federal platform 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 the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP, 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 SBE–FP issuers. The benefits provided to issuers in SBE–FPs by the federal government 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 QHP enrollment functions under § 155.400. The user fee rate for SBE–FPs is calculated based on the proportion of user fee eligible FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. Based on this methodology, we proposed to charge issuers offering QHPs through an SBE–FP a user fee rate of 2.5 percent of the

¹⁵⁰ U.S. Department of Commerce Bureau of Economic Analysis (BEA) Table 3.12 Government Social Benefits. Available at https://apps.bea.gov/iTable/iTable.cfm?reqid=19&step=3&isuri=1&categories=survey@nipa_table_list=110.

monthly premium charged by the issuer for each policy under plans offered through an SBE-FP. This rate is lower than the 3.0 percent user fee rate that we had established for benefit year 2019. The lower user fee rate for SBE-FP issuers for the 2020 benefit year reflects our estimates of premium increases and enrollment decreases for the 2020 benefit year. We sought comment on this proposal.

We are finalizing the FFE and SBE-FP user fee rates for the 2020 benefit year at 3.0 and 2.5 percent of monthly premiums, respectively, as proposed.

Comment: The majority of commenters supported HHS' efforts to reduce the costs of operating the FFE and reducing FFE and SBE-FP user fee rates. Some commenters noted HHS should lower the user fee rates further or even eliminate the user fee collection to promote increased competition, improve access to coverage, and reduce issuer duplication of effort in the off-Exchange market. However, other commenters did not support the reduction of FFE and SBE-FP user fee rates, asking that HHS maintain current user fee rates. Several of these commenters encouraged HHS to either re-invest excess funds into consumer outreach and education activities or otherwise restore funding of those activities to 2017 levels. One commenter suggested HHS should use excess funds to support outreach to the uninsured, especially in rural areas. Another commenter noted that increased investments to marketing and outreach will result in lower Exchange premiums due to an improved risk mix, which would outweigh the costs of premium increases from a higher user fee rate. Other commenters noted that HHS needs to ensure that it is investing sufficient funds in improvements to FFE information technology.

Response: We are finalizing the FFE and SBE-FP user fee rates for the 2020 benefit year at 3.0 and 2.5 percent of monthly premiums, respectively, as proposed. 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, and we will establish the user fee rate that is reasonable and necessary to fully fund user fee eligible Exchange operation costs. As we discussed in our proposal to reduce the FEE and SBE-FP user fee rates for the 2020 benefit year, we developed the user fee rates based upon estimated costs, enrollment, and premiums. We specifically noted that the reduced user fee rates, which we are finalizing as proposed, incorporate our estimates of premium increases and enrollment decreases for the 2020

benefit year, and are not solely a reflection of the total expenses estimated to operate and maintain the Federal platform and FFE operations. We also reiterate that any collections in excess of user fee eligible costs for a given year are rolled over for spending to the subsequent year's user fee eligible expenses. Finally, we note that outreach and education efforts will continue to be evaluated annually and funded at the appropriate level. HHS remains committed to providing a seamless enrollment experience for Federal platform consumers. We are committed to applying resources to cost-effective, high-impact outreach and marketing activities that offer the highest return on investment.

Comment: One commenter noted HHS should further reduce user fees for issuers who take on additional activities administered by the FFE, such as direct enrollment and increased marketing and outreach.

Response: All issuers offering QHPs on the FFEs and SBE-FPs receive the same respective special benefits HHS provides through the activities associated with operating the Federal platform. The amount of special benefits HHS offers issuers does not change even if an issuer chooses to take on additional activities, which may overlap with the Federal platform functions. Further, issuers who choose to participate as an Enhanced Direct Enrollment partner still derive special benefits from costs HHS incurs to operate the Federal platform. As such, our analysis of user fee eligible costs does not justify an additional reduction to the user fee rate beyond what is being finalized in this rule for the 2020 benefit year. We continue to annually review changes in estimated user fee eligible costs due to economies and structural improvements being made to the federal activities that work in concert to improve the enrollment and eligibility determination functions for issuers offering QHPs through FFEs and SBE-FPs, as well as the plan certification activities for FFEs.

Comment: Several commenters requested more transparency from HHS on how we set the FFE and SBE-FP user fee rates and urged HHS to make available a breakdown of Exchange expenses by functional area. Commenters noted more transparency would reduce uncertainty among SBE-FP states, allow states to better ascertain the cost effectiveness of transitioning to a different exchange model, and help identify areas for additional cost savings. One commenter noted HHS should issue a report outlining the use of Exchange user fees for past plan years

and annually moving forward. Another commenter noted HHS should provide its specific assumptions for marketing and outreach budget levels through the annual payment notice process. One commenter requested HHS ensure no user fees are diverted to non-Exchange functions and urged HHS to provide refunds or credits to issuers for funds collected in excess of Exchange costs.

Response: The FFE and SBE-FP user fee rates for the 2020 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 2020 benefit year. These estimates yielded an FFE user fee rate of 3.0 percent of premiums, and an SBE-FP user fee rate of 2.5 percent of premiums, based on the proportion of FFE functions that apply to SBE-FPs. We expect these user fee rates to result in adequate collections based on our current estimates of enrollment, premiums, and user fee eligible costs.

User fee eligible costs are estimated in advance of the benefit year and are based upon contract costs that are not yet finalized. We will continue to outline user fee eligible functional areas in the Payment Notice, and will evaluate contract activities related to operation of the federal Exchange user fee eligible functions.¹⁵¹ The categories that are considered user fee eligible include activities that provide special benefits to issuers offering QHPs through the Federal platform, and do not include activities that are provided to all issuers. For example, functions related to risk adjustment program operations, which are provided to all issuers in states where HHS operates the risk adjustment program (all 50 states and the District of Columbia for the 2020 benefit year), are not included in the FFE or SBE-FP user fee eligible costs. However, costs related to Exchange-related information technology, health plan review, management and oversight, eligibility and enrollment determination functions including the call center, and consumer information and outreach are incorporated in the FFE user fee eligible costs. SBE-FPs conduct their own health plan reviews and consumer information and outreach, and therefore, the SBE-FP user fee rate is determined

¹⁵¹ See the following FY2019 budget documents for a reference to estimates provided for the President's budget. HHS FY2019 Budget in Brief. Available at <https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf>; CMS FY2019 Justification of Estimates for Appropriations Committees. Available at <https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2019-CJ-Final.pdf>.

based on the portion of FFE costs that are also applicable to issuers offering QHPs through SBE-FPs.

Comment: One commenter noted HHS should lower the SBE-FP user fee rate to 1.5 percent of premiums to better reflect the current stability of the Exchange information technology and outreach and marketing expenses borne by the SBE-FP states, and because HHS likely received excess funds in the 2018 and 2019 benefit years due to the increases in Exchange premiums attributable to the elimination of CSR payments and introduction of silver loading.

Response: The final SBE-FP user fee rate for the 2020 benefit year of 2.5 percent of premiums is based on HHS' 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 2.5 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, should be charged proportionally for the special benefits provided by the Federal platform. As described in this rule, user fee eligible cost estimates are reviewed on an annual basis and developed in advance of the benefit year. If necessary, we will apply an overcollection of user fee funds to user fee eligible expenses in subsequent benefit years, as permissible. As noted in this rule, anticipated Exchange premiums are one factor HHS considers when developing the FFE and SBE-FP user fee rates. HHS agrees that increases in premiums, all other factors being equal, should place downward pressure on the FFE and SBE-FP user rates. Indeed, we are finalizing our proposal to reduce both the FFE and SBE-FP user fee rates by 0.5 percentage points based upon estimates of increased premiums and decreased enrollments for the 2020 benefit year. Although the commenter is correct that HHS reduced its outreach and education costs in 2018 and 2019, we do not charge SBE-FPs for these costs as outreach and education activities are SBE-FPs' responsibility. Therefore any further reduction of outreach and education activities would not be reflected in the SBE-FP user fee rate.

Comment: One commenter requested the user fee rate be charged as a fixed dollar amount instead of a percent of

premium because HHS' Exchange costs are fixed.

Response: As we have stated in prior payment notices, the FFE and SBE-FP user fee rates will continue to be assessed as a percent of the monthly premium charged by participating issuers. Setting the user fee as a percent of premium ensures that the user fee generally aligns with the issuer's use of the enrollment and eligibility functions performed by the FFE, and ensures that user fee charges reflect Exchange enrollment.

3. Silver Loading

Section 1402 of the PPACA requires issuers to provide CSRs to help make coverage affordable for certain low- and moderate-income consumers who enroll in silver level QHPs, as well as Indians who enroll in QHPs at any metal level. Section 1402 of the PPACA further states that HHS will reimburse issuers for the cost of providing CSRs. Until October 2017, the federal government relied on the permanent appropriation at 31 U.S.C. 1324 as the source of funds for federal CSR payments to issuers. However, on October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury with a legal opinion indicating that the permanent appropriation at 31 U.S.C. 1324 cannot be used to fund CSR payments to insurers. In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides an appropriation. In response to the termination of CSR payments to issuers, many issuers increased premiums in 2018 and 2019 only on silver level QHPs to compensate for the cost of CSRs—a practice sometimes referred to as “silver loading” or “actuarial loading.” Because premium tax credits are generally calculated based on the second-lowest cost silver plan offered through the Exchange, this practice has led to consumers receiving higher premium tax credits. The cost of these higher premium tax credits are being borne by taxpayers.

Silver loading is the result of Congress not appropriating funds to pay CSRs, with the result being an increase to the premiums of benchmark plans used to calculate premium tax credits, and the federal deficit.¹⁵² The Administration

¹⁵² CBO estimates that, under current law, outlays for health insurance subsidies and related spending will rise by about 60 percent over the projection period, increasing from \$58 billion in 2018 to \$91 billion by 2028. See CBO report *The Budget and Economic Outlook: 2018 to 2028*, April 2018, page

supports a legislative solution that would appropriate CSR payments and end silver loading.¹⁵³ In the absence of Congressional action, we sought comment on ways in which HHS might address silver loading, for potential action in future rulemaking applicable not sooner than plan year 2021. Consistent with our discussion in the proposed rule, we are not finalizing any change in policy for silver loading in this final rule.

Comment: All commenters supported silver loading as an option to maintain consumer affordability and participation. The majority of commenters urged HHS to continue to allow states to determine how to implement CSR loading. Some commenters expressed opposition to the practice of “broad loading,” in which issuers increase premiums on all metal level plans (on- and off-Exchange) to mitigate the lack of CSR reimbursement. Those commenters stated that increasing premiums for all plans would force unsubsidized consumers to pay higher premiums and would decrease APTC amounts. Commenters noted the reduction in financial assistance, and large premium swings from year to year will cause consumer confusion and instability in the Exchanges, and such market disruption may lead to issuers leaving the Exchanges.

Some commenters suggested that HHS should phase in a limitation on silver loading after permanent and stable funding is provided, to mitigate significant out-of-pocket costs for eligible enrollees who would see the amount of their premium tax credit reduced.

Response: We appreciate the comments received and will take them into consideration in determining whether future action is appropriate.

4. Essential Health Benefits Package

a. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

In the 2019 Payment Notice, we finalized options for states to select new EHB-benchmark plans starting with the 2020 benefit year. Under § 156.111, a state may modify its EHB-benchmark plan by:

51. Available at <https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53651-outlook.pdf>.

¹⁵³ The President's Fiscal Year 2020 Budget includes a legislative proposal to provide for a mandatory appropriation to make CSR payments for calendar year 2020. The proposal also allows for CSR payments to issuers who did not “silver-load” or “broad-load” from the 4th quarter of 2017 through the end of 2019.

(1) Selecting the EHB-benchmark plan that another state used for the 2017 plan year;

(2) Replacing one or more EHB categories of benefits 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; or

(3) Otherwise selecting a set of benefits that would become the state's EHB-benchmark plan.

Under any of these three options, the EHB-benchmark plan will also have to meet additional standards, including scope of benefits requirements. These options were intended to provide states with more flexibility in the selection of their EHB-benchmark plan than had previously existed. In the 2019 Payment Notice, we encouraged states to consider the potential impact on vulnerable populations as they select their new EHB-benchmark plans, and the need to educate consumers on benefit design changes. We also remind states to inform issuers of such changes should they select a new EHB-benchmark plan.

In the proposed rule, we stated that we believe that the three new options—the third in particular—may provide states with additional flexibility to address the opioid epidemic. For example, Illinois made changes to its EHB-benchmark plan for plan year 2020 that aim to reduce opioid addiction and overdose by including in its EHB-benchmark plan alternative therapies for chronic pain, restricting access to prescription opioids, and expanded coverage of mental health and substance use disorder treatment and services.¹⁵⁴ We continue to encourage other states to explore whether modifications to their EHB-benchmark plan would be helpful in fighting the opioid epidemic.

Additionally, the 2019 Payment Notice stated that we would propose subsequent EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters. Accordingly, we proposed May 6, 2019 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2021 plan year. We noted that this deadline would be delayed, if necessary, to be on or after the effective date of this final rule. To give advance notice to states and issuers, we simultaneously proposed May 8, 2020 as the deadline for states to submit the required documents for

the state's EHB-benchmark plan selection for the 2022 plan year. Although not a requirement, we recommend states submit applications at least 30 days prior to the submission deadlines to ensure completion of their documents by the proposed deadlines. We recognize that these deadlines are earlier in the year than the July 2, 2018 deadline for the state's EHB-benchmark plan selection for the 2020 plan year. These deadlines would allow for an earlier finalization of a state's EHB-benchmark plan and a longer time period for issuers to develop plans that adhere to their state's new EHB-benchmark plan. States would have to have completed the required public comment period and submit a complete application by the deadlines.

Comment: We received a number of comments supporting our encouragement of states to explore whether modifications to their EHB-benchmark plan would be helpful in fighting the opioid epidemic. Some commenters supported such modifications, but only to the extent they do not impose strict limits on the doses of opioids for treating pain, which commenters stated could come at the expense of individuals who need access to these medications to treat their conditions.

Response: We appreciate these comments, and continue to urge states to consider taking all appropriate action to address the opioid epidemic, including by making modifications to their EHB-benchmark plans.

Comment: Several commenters supported the EHB-benchmark selection submission deadline as proposed. A few commenters expressed their desire for HHS to extend the submission deadline to allow states more time to evaluate their EHB-benchmark plans, and consider submitting changes to HHS.

Response: We are finalizing May 6, 2019 as the 2021 plan year EHB-benchmark plan selection submission deadline and May 8, 2020 as the 2022 plan year EHB-benchmark plan submission deadline, as proposed. We recognize the proposed submission deadline for plan year 2021 is earlier in the year than the deadline for the previous plan year and also before the rule's effective date. However, unlike the 2020 submission deadline, which we finalized in the 2019 Payment Notice concurrently with the policy at § 156.111(a), we are not finalizing any new policy at § 156.111(a) for 2021. Because states have now had over a year to determine whether to make EHB-benchmark plan changes for 2021, we believe that the deadline gives them ample time to submit the required

documents to HHS and that they have been preparing for this deadline since proposed in the proposed rule. In having an earlier submission date than for the 2020 plan year, issuers and other stakeholders would have more time to understand benchmark plan changes made by the state and for issuers to design plans that will comply with changes to the benchmark. We do not believe that finalizing a later date, including a date on or after the rule's effective date, would give issuers sufficient time to design plans.

b. Provision of EHB (§ 156.115)

In the 2019 Payment Notice, we also finalized a policy through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that the deadlines applicable to state selection of a new benchmark plan would also apply to this state opt-in process. We therefore proposed May 6, 2019 as the deadline for states to notify us that they wish to permit between-category substitution for the 2021 plan year and May 8, 2020 as the deadline for states to notify us that they wish to permit between-category substitution for the 2022 plan year. We noted that the 2021 plan year deadline would be delayed, if necessary, to be on or after the effective date of this final rule. States wishing to make such an election must do so via the EHB Plan Management Community.

Comment: A few commenters supported the proposed submission deadline.

Response: We are finalizing the submission deadlines as proposed. The deadline for the 2021 plan year is May 6, 2019, and the deadline for the 2022 plan year is May 8, 2020. Although the 2021 plan year deadline is before the rule's effective date, we believe that this is necessary in order for issuers to have sufficient time to design plans that take into account any benefit substitution changes.

c. Prescription Drug Benefits (§ 156.122)

i. Mid-Year Formulary Change Reporting Requirement

At new § 156.122(d)(3), we proposed that for plan years beginning on or after January 1, 2020, QHP issuers in the FFEs would be required to notify HHS annually in an HHS-specified format of any mid-year formulary changes made in the prior plan year consistent with the proposed changes to § 147.106(e). QHP issuers in the FFEs would be required to report the name of the drug being removed from the formulary, dosage, name of the generic equivalent, the Rx Norm Concept Unique Identifier

¹⁵⁴ IL DOI Press Release, "Illinois becomes first and only state to change Essential Health Benefit-benchmark plan," Aug. 27, 2018. Available at https://www2.illinois.gov/HHSNews/18098-DOI-EssentialHealth_Benefit-benchmark_plan_Release.pdf.

(RxCUI) associated with the brand and generic drug, if the brand drug was moved to a higher cost sharing tier or removed from the formulary, in a manner specified in the forthcoming PRA associated with this final rule. We proposed to use this information to understand how the proposed change would affect QHP enrollees. We sought comment on this proposal.

Comment: Several commenters supported the collection as proposed. Other commenters suggested expanding the submission to require issuers to report to mid-yearly formulary changes to the state in addition to HHS. Other issuers suggested HHS use existing data sources to collect the information.

Response: We are not finalizing this collection because we are not finalizing the proposal in this rule at § 147.106(e). For more information about that proposal, see the preamble to § 147.106.

ii. Therapeutic Substitution

We solicited comments on two additional drug policies intended to consider the potential of therapeutic substitution. First, the prescription drug market became more efficient after several states passed laws that allowed for generic substitution. Similarly, therapeutic substitution, which consists of substituting chemically different compounds within the same class for one another,¹⁵⁵ could be employed to improve the efficiency of the pharmaceutical market. We acknowledged that many stakeholders are opposed to therapeutic substitution and that there are concerns regarding efficacy, adverse effects, drug interactions, and different indications for drugs within a class. If therapeutic substitution were to become commonplace, efficient systems that allow for seamless communication among prescribers, pharmacies, and insurance companies would need to be in place. Therapeutic substitution may help decrease drug costs if it can be implemented in a way that does not negatively affect quality and access to care. We solicited comment on whether therapeutic substitution and generic substitution policies should both be pursued since each of the two options might offset any potential premium impact of the other, as well as whether certain drug categories and classes are better suited to therapeutic substitution than others. We also sought comment on any existing standards of practice for therapeutic substitution and whether

those standards are nationally recognized and readily available for providers to use.

Second, the majority of issuers, employers, and pharmacy benefit managers negotiate price discounts and rebates from pharmaceutical manufacturers by implementing tiered formularies, which link patients' cost-sharing obligations to the list price of each drug. Tiered formularies have been successful in attenuating the growth in pharmaceutical spending and overall drug spending. However, in recent years, drug spending has again increased. Reference-based pricing is one strategy for attenuating increases in pharmaceutical spending. Reference-based drug pricing occurs when an issuer in a commercial market covers a group of similar drugs, such as within the same therapeutic class, up to a set price, with the enrollee paying the difference in cost if the enrollee desires a drug that exceeds the set (reference) price.¹⁵⁶ Implementation of reference-based pricing for drugs could bring down overall health plan costs, and perhaps premium increases, while increasing consumer out-of-pocket costs in some instances. Durable medical equipment benefits like eyeglasses and contacts are sometimes covered in a similar manner. Although reference-based pricing is often discussed in the context of network adequacy and using certain providers within a particular network who are willing to accept a reference price, we do not intend for this drug policy to have network implications, and issuers are currently free to impose lower cost sharing for drugs obtained via mail order. We sought comment on the opportunities and risks of implementing or incentivizing reference-based pricing for prescription drugs.

Comment: Some commenters did not support the implementation of a policy related to therapeutic substitution due to concerns regarding efficacy, adverse effects, drug interactions, different indications for drugs within a class and the potential of such a policy to jeopardize consumers' access to clinically indicated drugs. Commenters noted that automatic therapeutic substitution overrides a treatment decision made between the patient and provider, which could put patients' health at risk. Additionally, commenters noted that they did not believe that the current health care system possesses the operational capacity to implement

therapeutic substitution without jeopardizing the quality of and access to care. Commenters who were supportive of therapeutic substitution stated they appreciated HHS' efforts to allow additional tools and flexibility to manage drug costs and recommended that biosimilars and interchangeable biologics be therapeutically substitutable as well.

One commenter supported the concept of reference-based pricing, but noted that implementation must be carefully considered. Commenters who opposed reference-based pricing stated they were not confident that there were transparency measures in place to enable reference-based pricing to be successful.

Two commenters requested that HHS postpone its consideration of implementing reference-based pricing until greater transparency is achieved throughout the entire pharmaceutical supply chain. One commenter noted that if HHS were to implement reference-based pricing, it should allow patients to request an exception from the balance billing requirement if a medication is medically necessary but exceeds the reference price. Two commenters were receptive to a policy related to reference-based pricing, noting that implementation could have a positive impact on pharmacy spending, but cautioned that because this type of pricing model may be somewhat new in the pharmacy space, it could initially cause member confusion. Some commenters cautioned that implementation of this initiative would require extensive member communication. Additionally, one commenter noted that HHS should study the various ways group benefit plans are already employing reference-based pricing before acting on regulatory requirements or incentives and cautioned against defining reference-based pricing explicitly before actually engaging in any formal regulatory activity concerning this practice, as premature definitions can be limiting.

Response: We appreciate these comments and will take them under consideration for any future rulemaking.

d. Prohibition on Discrimination (§ 156.125)

Opioid misuse and addiction is a serious national crisis that affects public health, as well as social and economic welfare. More than 115 people in the United States die each day from opioid

¹⁵⁵ Pengxiang, L., Sanford Schwartz, J., & Doshi, J.A. (2016). Impact of Cost Sharing on Therapeutic Substitution: The Story of Statins in 2006. *Journal of the American Heart Association*.

¹⁵⁶ Robinson, J.C., Whaley, C.M., & Brown, T.T. (2017). Association of Reference Pricing with Drug Selection and Spending. *New England Journal of Medicine*, 377:658665. Doi:10.1065/NEJMsa1700087.

overdoses.¹⁵⁷ The Centers for Disease Control and Prevention estimates that the total costs of prescription opioid misuse alone in the United States is \$78.5 billion per year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.¹⁵⁸ It has been an active Public Health Emergency, as determined by the Secretary under 42 U.S.C. 247d, since October 26, 2017.¹⁵⁹

Several factors have influenced the opioid crisis, including: the opioid pharmaceutical manufacturing and supply chain industry; deficient patient and provider pain management education; rogue pharmacies and unethical physician prescribing; and the insufficient availability of treatment services, including Medication-Assisted Treatment (MAT).¹⁶⁰

MAT is the use of medication approved by the FDA for addiction detoxification, relapse prevention, or maintenance treatment, in combination with counseling and behavioral therapies to treat substance use disorders and prevent overdose through detoxification, relapse prevention, and maintenance treatment.¹⁶¹ MAT has

proven to be clinically effective in treating opioid use disorder and to significantly reduce the need for inpatient detoxification services for individuals with opioid use disorder.¹⁶²

Despite this evidence, and despite the attention paid to the nationwide opioid Public Health Emergency, there is not comprehensive, nationwide coverage of the drugs used in MAT, at least among QHP issuers. A review of QHP issuer formularies in the 39 FFE and SBE-FP states for which we have data reveals that, while many QHPs cover all four MAT drugs, not all do. Specifically, for plan year 2018, 2,553 QHPs (95 percent) in these 39 FFE and SBE-FP states cover all four of these drugs; 105 QHPs (4 percent) cover three; and 25 QHPs (<1 percent) cover two. Given the effectiveness of MAT and the severity of the nationwide opioid Public Health Emergency, we encourage every health insurance plan to provide comprehensive coverage of MAT, even if the applicable EHB-benchmark plan does not require the inclusion of all four MAT drugs on a formulary. In the proposed rule, we encouraged issuers to take every opportunity to address opioid use disorder, including increasing access to MAT and destigmatizing its use.¹⁶³

In addition, we stated that we have become aware that a MAT drug's inclusion on a formulary does not necessarily ensure coverage of that drug when administered for MAT. We stated that we are aware that some issuers utilize plan designs which exclude coverage of certain drugs when used for MAT while the same drugs are covered for other medically necessary purposes, such as analgesia or alcohol use disorder. Under § 156.125, which implements the provision prohibiting discrimination, an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's

age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

We reminded issuers that any indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices is potentially discriminatory. As is the case for any EHB, issuers are expected to impose limitations and exclusions on the coverage of benefits to treat opioid use disorder, including the drugs used for MAT or any associated benefit such as counseling or drug screenings, based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. If a plan excludes certain treatment of opioid use disorder, but covers the same treatment for other medically necessary purposes, the issuer must be able to justify such an exclusion with supporting documentation explaining how such a plan design is not discriminatory.

We noted that a similar standard is imposed under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (section 2726 of the PHS Act).¹⁶⁴ Under regulations implementing the EHB requirements,¹⁶⁵ the requirements of MHPAEA are extended to issuers of non-grandfathered health insurance coverage in the individual and small group markets, both on and off the Exchange. Under HHS regulations at § 146.136 implementing MHPAEA, if a drug is offered under a plan for treatment of a medical condition or surgical procedures but is excluded for MAT purposes to treat a substance use disorder, that is considered to be a nonquantitative treatment limitation.¹⁶⁶ A nonquantitative treatment limitation cannot be imposed on mental health or substance use disorder benefits in any classification¹⁶⁷ unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards or other factors used in applying the limitation to the mental health or substance use disorder

¹⁵⁷ CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: US Department of Health and Human Services, CDC; 2017. <https://wonder.cdc.gov>.

¹⁵⁸ Florence C.S., Zhou C., Luo F., Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Med Care*. 2016; 54(10):901–906. doi:10.1097/MLR.0000000000000625. Available at <https://www.ncbi.nlm.nih.gov/pubmed/27623005>.

¹⁵⁹ As determined by Acting Secretary Eric D. Hargan. “Determination that a Public Health Emergency Exists”. October 26, 2017. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx>. Renewed by Acting Secretary Hargan. “Renewal of Determination that a Public Health Emergency Exists”. January 19, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-24Jan2018.aspx>. Renewed by Secretary Alex M. Azar II. “Renewal of Determination that a Public Health Emergency Exists”. April 20, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-20Apr2018.aspx>. Renewed by Secretary Azar. “Renewal of Determination that a Public Health Emergency Exists”. July 19, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-19July2018.aspx>. Renewed by Secretary Azar. “Renewal of Determination that a Public Health Emergency Exists”. October 18, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-18Oct2018.aspx>. Renewed by Secretary Azar. “Renewal of Determination that a Public Health Emergency Exists”. January 17, 2019. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-17Jan2019.aspx>.

¹⁶⁰ “The President’s Commission on Combating Drug Addiction and the Opioid Crisis”. Pages 19–23. November 1, 2017. Available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

¹⁶¹ There are four drugs currently used in MAT: Buprenorphine; naltrexone; buprenorphine in combination with naloxone; and methadone.

¹⁶² “Medication and Counseling Treatment”. September 28, 2015. Available at <https://www.samhsa.gov/medication-assisted-treatment/treatment>.

¹⁶³ “For many people struggling with addiction, failing to offer MAT is like trying to treat an infection without antibiotics. . . . We know that there is sometimes stigma associated with MAT—especially with long term therapy. But someone on MAT, even one who requires long-term treatment, is not an addict. They need medicine to return to work; re-engage with their families; and regain the dignity that comes with being in control of their lives. These outcomes are literally the opposite of how we define addiction. Our fellow citizens who commit to treatment should not be treated as pariahs—they are role models.” Azar, Alex. Plenary Address to National Governors Association, February 24, 2018. Available at <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-address-to-national-governors-association.html>.

¹⁶⁴ MHPAEA originally applied to large group health plans and large group health insurance coverage, and PPACA extended it to apply to individual health insurance coverage.

¹⁶⁵ § 156.115(a)(3).

¹⁶⁶ For examples of nonquantitative treatment limitations, see § 146.136(c)(4)(ii).

¹⁶⁷ Classifications under MHPAEA are as follows: Inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs. § 146.136(c)(2)(ii).

benefits in the classification are comparable to, and are applied no more stringently than the processes, strategies, evidentiary standards and other factors used in applying the limitation to medical/surgical benefits in the same classification. In other words, the issuer must demonstrate that, as written and in operation, the processes, strategies, evidentiary standards, and other factors it applied in deciding that the drug is covered for medical/surgical purposes, are comparable to those it used in deciding that the drug is not covered for MAT purposes, and that there are no separate limitations that apply only for mental health or substance use disorder benefits.¹⁶⁸

We also noted that federal civil rights laws, such as title II of the Americans with Disabilities Act and section 504 of the Rehabilitation Act, prohibit discrimination against individuals who participate in or have completed substance use disorder treatment, including MAT.

Comment: Many commenters supported our continued interpretation of the prohibition on discrimination as it applies to the coverage of treatments for opioid use disorder. Many commenters supported our recommendation that issuers provide comprehensive coverage of MAT, thereby increasing access to MAT and destigmatizing its use. Several commenters suggested that HHS require coverage of all four drugs used in MAT, and a few commenters cautioned against such a requirement.

A number of comments outside the scope of this rule encouraged HHS and states to take aggressive enforcement actions against all discriminatory benefit designs, including plan designs that may violate MHPAEA. A number of commenters suggested that discriminatory benefit designs exist with regards to women's health benefits and benefits for the treatment of sexually transmitted diseases.

Response: We appreciate these comments and will take them under consideration as we continue to monitor and implement strategies to address discriminatory benefit designs and the opioid epidemic.

e. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the PPACA directs the Secretary to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the rate of increase for three parameters detailed in the PPACA: (1)

The maximum annual limitation on cost sharing (defined at § 156.130(a)); (2) the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)); and (3) the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code (see section 4980H(c)(5) of the Code). Section 1302(c)(4) of the PPACA and § 156.130(e) provide 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 the regulations provide that this percentage will be published in the annual HHS notice of benefit and payment parameters. To calculate the premium adjustment percentage for the 2020 benefit year, we calculate the percentage by which the average per capita premium for health insurance coverage for 2019 exceeds the average per capita premium for health insurance for 2013, and round the resulting percentage to 10 significant digits. The resulting premium index reflects cumulative, historic growth in premiums from 2013 onwards.

The 2015 Payment Notice (79 FR 13743) and 2015 Market Standards Rule (79 FR 30240) established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage for the 2015 benefit year and beyond. Beginning with the 2015 benefit year, the premium adjustment percentage was 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. In the proposed 2015 Payment Notice, we proposed that the premium adjustment percentage be calculated based on the projections of average per enrollee private health insurance premiums. Based on comments received, we finalized the 2015 Payment Notice to instead use per enrollee employer-sponsored insurance premiums in the methodology for calculating the premium adjustment percentage. We chose employer-sponsored insurance premiums because they reflected trends in health care costs without being skewed by individual market premium fluctuations resulting from the early years of implementation of the PPACA market reforms. We adopted this methodology in subsequent Payment Notices for 2016 through 2019, but noted in the 2015 Payment Notice

that we may propose to change our methodology after the initial years of implementation of the market reforms, once the premium trend is more stable.

As discussed in the 2015 Payment Notice, we considered four criteria when finalizing the premium adjustment percentage methodology for the 2015 benefit year: (1) *Comprehensiveness*—the premium adjustment percentage should be calculated based on the average per capita premium for health insurance coverage for the entire market, including the individual and group markets, and both fully insured and self-insured group health plans; (2) *Availability*—the data underlying the calculation should be available by the summer of the year that is prior to the calendar year so that the premium adjustment percentage can be published in the annual HHS notice of benefit and payment parameters in time for issuers to develop their plan designs; (3) *Transparency*—the methodology for estimating the average premium should be easily understandable and predictable; and (4) *Accuracy*—the methodology should have a record of accurately estimating average premiums. We continue to consider these criteria as we evaluate other sources of premium data that could be used in calculating the premium adjustment percentage.

To date, the NHEA projections of per enrollee employer-sponsored insurance premiums have also been used by the Department of the Treasury and the IRS 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.¹⁶⁹ The applicable percentage in section 36B(b)(3)(A) of the Code is used to determine the amount an individual must contribute to the cost of an Exchange QHP and thus, relates to the amount of the individual's premium tax credit. This is because, in general, an individual's premium tax credit is the lesser of (1) the premiums paid for the Exchange QHP, and (2) the excess of the premium for the benchmark plan over the contribution amount. The contribution amount is the product of the individual's household income and the applicable percentage.

The required contribution percentage in section 36B(c)(2)(C) of the Code is used to determine whether an offer of employer-sponsored insurance is considered affordable for an individual, which relates to eligibility for the premium tax credit because an individual with an offer of affordable employer-sponsored insurance that

¹⁶⁸ See § 146.136(c)(4)(iii), Ex. 10.

¹⁶⁹ IRS Rev. Proc. 2014–37.

provides minimum value is ineligible for the premium tax credit. Specifically, an offer of employer-sponsored insurance is considered affordable for an individual if the employee's required contribution for employer-sponsored insurance is less than or equal to the required contribution percentage (set at 9.5 percent in 2014) of the individual's household income.¹⁷⁰

Section 36B(b)(3)(A)(ii) of the Code generally provides that the applicable percentages are to be adjusted after 2014 to reflect the excess of the rate of premium growth over the rate of income growth for the preceding year. Section 36B(c)(2)(C) of the Code provides that the required contribution percentage is to be adjusted after 2014 in the same manner as the applicable percentages are adjusted in section 36B(b)(3)(A)(ii) of the Code. As noted in this rule, the Department of the Treasury and the IRS have issued guidance providing that the rate of premium growth for purposes of these section 36B provisions is based on per enrollee spending for employer-sponsored insurance as published in the NHEA.¹⁷¹

In the proposed rule, we proposed to modify the premium growth measure that we used to calculate the premium adjustment percentage for the 2020 benefit year and beyond. We proposed to use a more comprehensive premium measure that captures increases across the market, including individual market premiums and employer-sponsored insurance premiums, for purposes of calculating the premium adjustment percentage. Specifically, we proposed to calculate the premium growth measures for 2013 and 2019 as private health insurance premiums minus premiums paid for Medigap insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees.

This premium measure is an adjusted private individual and group market health insurance premium measure, which is similar to NHEA's private health insurance premium measure. NHEA's private health insurance premium measure includes premiums for employer-sponsored insurance, "direct purchase insurance," which includes individual market health insurance purchased directly by consumers from health insurance

issuers, both on and off the Exchanges, and Medigap insurance, and the medical portion of accident insurance ("property and casualty" insurance). The measure we proposed to use is published by NHEA and includes NHEA estimates and projections of employer-sponsored insurance and direct purchase insurance premiums, but we proposed to exclude Medigap and property and casualty insurance from the premium measure since these types of coverage are not considered primary medical coverage for individuals who elect to enroll. We proposed to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) so that the premium growth measure more closely reflects premium trends for all individuals primarily covered in the private health insurance market since 2013, and we anticipated that the proposed change to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) would additionally reduce federal premium tax credit expenditures, if the Department of the Treasury and the IRS were to adopt the proposed change.

Using the private health insurance premium measure (excluding Medigap and property and casualty insurance), we proposed that the premium adjustment percentage for 2020 be the percentage (if any) by which the most recent NHEA projection of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2019 (when proposed, \$6,468) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 (when proposed, \$4,987).¹⁷² Using this formula, the proposed premium adjustment percentage for the 2020 benefit year was 1.2969721275 (\$6,468/\$4,987), which represented an increase in private health insurance (excluding

Medigap and property and casualty insurance) premiums of approximately 29.7 percent over the period from 2013 to 2019.

We are finalizing the proposal to use per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) in the premium adjustment percentage calculation. As we discussed in the proposed rule, immediate application of this change will result in a faster premium growth rate for the foreseeable future than if we continued to use only employer-sponsored insurance premiums as in prior benefit years. We anticipate that this change will have several impacts on the health insurance market. As explained in this rule, the premium adjustment percentage is used to set the rate of increase for the maximum annual limitation on cost sharing, the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code. Accordingly, a premium adjustment percentage that reflects a faster premium growth rate would result in a higher maximum annual limitation on cost sharing, a higher required contribution percentage, and higher employer shared responsibility payment amounts than if the current premium adjustment percentage premium measure (employer-sponsored insurance only) were adopted for the 2020 benefit year.

In the proposed rule, we stated that, if we finalize a change to the premium measure used in the premium adjustment percentage for the 2020 benefit year, we expect the Department of the Treasury and the IRS to issue additional guidance to adopt the same premium measure for purposes of future indexing of the applicable percentage and required contribution percentage under section 36B of the Code. Additionally, the Health Insurance Providers Fee established under section 9010 of the PPACA also takes the measure of premium growth used for the applicable percentage in section 36B(b)(3)(A)(ii) of the Code into consideration for purposes of calculating the fee for 2019 and beyond.¹⁷³ We expect the Department of the Treasury and the IRS to adopt the premium measure that results in a faster premium growth rate that we are

¹⁷² The 2013 and 2019 per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) figures used for this calculation reflect the latest NHEA data, which was updated between the publication of the proposed rule and this final rule, on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the "NHE Projections 2018–2027—Tables" link located in the Downloads section at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. A detailed description of the NHE projection methodology is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf>.

¹⁷⁰ See also IRS Notice 2015–87, Q&A 12 for discussion of the adjustment of the required contribution percentage as applied for certain purposes under sections 4980H and 6056 of the Code.

¹⁷¹ See IRS Rev. Proc. 2014–37 (<https://www.irs.gov/pub/irs-drop/rp-14-37.pdf>).

¹⁷³ See PPACA section 9010(e)(2). However, under section 4003 of Public Law 115–120, Division D—Suspension of Certain Health-Related Taxes, enacted on January 22, 2018, the collection of the Health Insurance Providers Fee is suspended for the 2019 calendar year.

finalizing, which will result in slightly higher Health Insurance Providers Fees imposed on health insurance issuers that are required to pay the fee, over the long term. We anticipate that health insurance issuers subject to the Health Insurance Providers Fee generally would pass the fee on to consumers, and that higher fees would increase premiums in the individual, small, and large group markets, although we anticipate that any premium increases would be very small. Additionally, as stated in the proposed rule, a faster premium growth measure and corresponding increase in the applicable percentage will increase the amount that individuals receiving the premium tax credit contribute towards premiums, thereby reducing federal outlays for the premium tax credit that had increased significantly in the 2018 benefit year as many issuers increased silver plan premiums to offset the cost of providing cost-sharing reductions to eligible enrollees without receiving cost-sharing reduction payments from the federal government.

We have updated the impact estimates in the Regulatory Impact Analysis of this final rule to reflect impact estimates provided by the Department of the Treasury, pending their anticipated adoption of the premium measure finalized in this rule.

Although commenters expressed concern about the impacts resulting from this change, as discussed later in the preamble of this final rule, we are finalizing the change as proposed—to use per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) as the premium growth measure for purposes of calculating the premium adjustment percentage. This approach allows us to achieve the statutory and regulatory goals of a more comprehensive and accurate measure of premium costs across the private market.

Using the proposed premium measure, the premium adjustment percentage is calculated as the difference between the percentage (if any) by which the most recent NHEA projection of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2019 (\$6,436) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 (\$4,991), carried out to 10 significant digits.¹⁷⁴ Using this formula,

the final premium adjustment percentage for 2020, rounded to 10 significant digits, using per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) is 1.2895211380 (\$6,436/\$4,991), which is an increase of approximately 29 percent over the period from 2013 to 2019.

Comment: All commenters on this topic expressed opposition to or concerns about the proposed change, many of whom indicated HHS should continue to use the current measure, employer-sponsored insurance premiums, to measure premium growth. Almost all commenters were concerned about the impact of the proposal on the health insurance market and individuals and families, citing HHS' estimates of the impacts in the Regulatory Impact Analysis, including a decrease in enrollment and increase in premiums and out-of-pocket costs for consumers.

Several commenters noted that individual market premiums should not be used to measure premium growth since 2013 because premiums have increased due to PPACA market reforms and federal policy and legislative changes, including changes in the composition of the individual market risk pool that occurred with the elimination of pre-existing condition exclusions, the inclusion of a richer benefit package and lower cost-sharing than typically provided in the individual market in 2013, the cessation of CSR payments, the reduction of the individual shared responsibility penalty to \$0, and the ending of the reinsurance program. Commenters stated these premium increases should not be included in the measure of premium growth because they are not based on utilization or cost of medical services.

Several commenters noted our methodology is flawed because the proposal starts with 2013 as the base year, but the indexing provisions of section 1401 of the PPACA start with “the calendar year after 2014” (2015) and then use the preceding year, or 2014 as the base year. They state that since

property and casualty insurance) used for this calculation reflect the latest NHEA data, which was updated between the publication of the proposed rule and this final rule, on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the “NHE Projections 2018–2027—Tables” link located in the Downloads section at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. A detailed description of the NHE projection methodology is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf>.

EHB did not go into effect until 2014, utilizing a base year earlier than 2014 does not compare the prices of like individual insurance products. Several commenters recommended HHS use a base year no earlier than 2018 (rather than 2013) to avoid inclusion of premium increases resulting from PPACA market reforms and other federal policy and legislative decisions. Some commenters noted that HHS considered and rejected adopting using individual market premiums in the premium measure for the premium adjustment percentage for the 2015 benefit year because the premium trend was not stable, and the premium trend is still not stable, citing the PPACA policy and legislative changes mentioned in this rule and that 2019 is the first year new rules have taken effect regarding short-term, limited-duration insurance (STLDI) plans and association health plans (AHP), which may further disrupt the market and increase premiums. One commenter recommended only using individual market premium increases for underlying medical trends (in other words, not including premium increases resulting from federal policy and legislative changes), while a few commenters indicated that the change is not statutorily required, and urged HHS to delay the change until the premium trend is more stable.

Several commenters stated HHS's justification provided for this change is inadequate and contrary to the legislative intent of the financial assistance structure of the PPACA. One commenter noted that the primary purpose of providing APTC to Exchange enrollees is so that the federal government, rather than low-income individuals and families, bears the burden of any premium increases in the individual market. A few commenters urged HHS to consider other ways to reduce federal expenditures, or to focus on efforts at lowering the overall cost of health care, rather than placing the burden on households. One commenter supported keeping federal costs reasonable, but was concerned about HHS doing so by way of reducing PTC to consumers, which will increase the number of uninsured individuals. Another commenter noted that while the proposed change will result in federal PTC savings (a decreased taxpayer burden), consumers receiving APTC are taxpayers, and that the negative effects of reducing their APTC would outweigh the benefits of lower tax burden.

Another commenter noted that the proposed change will impact the coverage “affordability” percentages

¹⁷⁴ The 2013 and 2019 per enrollee premiums for private health insurance (excluding Medigap and

that IRS releases each spring, which are used by applicable large employers to determine the affordability of their offers of coverage for purposes of the employer shared responsibility provisions. As such, the commenter urged HHS to work closely with the IRS on the timing of any change and recognize that employer plans rely on the timely release of this data each spring for their annual plan-development processes.

Response: As stated earlier in this preamble, we are finalizing our proposal to calculate the premium adjustment percentage using a measure of premium growth that accounts for individual market health insurance premiums, as well as employer-sponsored insurance. Section 1302(c)(4) of the PPACA and § 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The purpose of this index is to measure growth in premiums, and the statute gives HHS flexibility to determine how to measure premium growth. Because the individual market is much smaller than the group market,¹⁷⁵ the increase in the percentage amount due to the change in methodology from measuring growth only in employer-sponsored insurance to using the new measure, which includes individual market health insurance, is quite small. Under the employer-sponsored insurance measure, the premium adjustment percentage would have been 1.2551737602. As stated above, under the new premium measure, the premium adjustment percentage is 1.2895211380, or a difference of approximately 3.4 percentage points. Therefore the new premium measure does not result in a significantly larger premium adjustment percentage; however, it does more comprehensively reflect the actual growth in premiums in the insurance markets.

As stated in the 2015 Payment Notice, we previously excluded premiums from the individual market because they were most affected by the significant changes in benefit design and market

composition in the early years of implementation of the PPACA market rules and were most likely to be subject to risk premium pricing. However, the PPACA is now past the initial years of implementation and issuers have had the opportunity to collect data on the risk composition of the individual market and adjust pricing accordingly. We have concluded, based on the general trend of stabilizing average premiums in the individual market,¹⁷⁶ that the likelihood of risk premium pricing has decreased. We further believe that individual market premium increases going forward will more accurately reflect true premium growth, thereby addressing the bases we identified in the 2015 Payment Notice for excluding individual market premiums from the premium adjustment percentage calculation. Therefore, we are finalizing our proposal to measure growth of premiums issuers charged enrollees more comprehensively, by no longer excluding individual market premiums.

While the PPACA does contain financial assistance provisions that shift costs from consumers to the federal government as noted by commenters, it also requires the Secretary to measure premium growth, so that the effects of premium growth can be reflected in other payment parameters. As such, although we are sensitive to commenters' concerns about the potential impact on consumers, we continue to believe that a premium growth measure that affects cost-sharing and payment parameters in the employer group markets and individual health insurance market should comprehensively reflect premium growth in all affected markets, and should not be limited to employer-sponsored insurance growth. In effect, this change is a technical correction for measuring premium growth, as the previous exclusion of individual market data was not the most comprehensive method of premium growth measurement, but was deemed necessary as a result of the premium instability in the individual market immediately following implementation of the PPACA market reforms.

Additionally, while we recognize comments noting that recipients of PTC are also taxpayers, reducing federal expenditures is not strictly a benefit to the federal government, but to all taxpayers, which includes those who are not PTC recipients. Further, we

understand that the premium adjustment percentage is relevant to determine the affordability of plans offered by applicable large employers for purposes of the employer shared responsibility provisions. We will continue to work closely with the Department of the Treasury and the IRS to timely release information on the indexing of the various PPACA provisions.

With respect to the comments requesting we use a different base year, the applicable statute, section 1302(c)(4) of the PPACA, requires the Secretary of HHS to establish a premium adjustment percentage that measures premium growth between the preceding calendar year (2019, in this case) and 2013. It is not legally permissible to change the base year to any year other than 2013, including the base year reflected in the PPACA section cited by commenters, section 1401.

Comment: Many commenters opposed the proposed change and indicated HHS should continue to use the current premium measure; however, a few of these commenters stated if HHS does adopt the proposed change it should change some aspects of its approach. A few commenters recommended that HHS consider a delayed or gradual phase in of individual market premiums over several years.

Response: As noted earlier in this section of the preamble, we believe that the growth of average premiums in the individual market has stabilized, and the reasons for excluding individual market premiums from the premium adjustment percentage calculation have been addressed.¹⁷⁷ Although we considered a phase-in approach, we do not believe that further delay meets the statutory and regulatory goals of using a comprehensive measure of premium growth. Additionally, as stated above, we believe that the individual market is now sufficiently stable to justify the immediate inclusion of individual market premium growth in the indexing measure going forward. For example, in plan year 2019, premiums for the second lowest cost silver plan decreased 2 percent, the first decrease in that premium measure since the advent of the PPACA.¹⁷⁸ As such, we believe it is appropriate to prioritize better achieving the goals of comprehensiveness and accuracy of the premium adjustment percentage methodology over the limited effect on mitigating impacts that implementing our proposal using a

¹⁷⁵Note for example the differences in enrollment between Employer-sponsored Insurance and Direct Purchase reflected in Table 17 of the "NHE Projections 2018–2027—Tables" available in the Downloads section at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. In 2020, the Office of the Actuary projects Employer-sponsored Insurance enrollment will be 176.6 million, and Direct Purchase enrollment will be 21.3 million.

¹⁷⁶ASPE Research Brief: 2019 Health Plan Choice and Premiums in Healthcare.gov States, showing a decrease in silver plan premiums for plan year 2019, available at <https://aspe.hhs.gov/system/files/pdf/260041/2019LandscapeBrief.pdf>.

¹⁷⁷See *id.*

¹⁷⁸*Id.*

phased-in approach would be likely to have.

Comment: One commenter provided a detailed explanation about what they viewed to be legal deficiencies with our statutory analysis, our justification for the proposed change, and the procedural approach. One commenter indicated that HHS has underestimated the significance of the proposed change's impact on the Health Insurance Providers Fee and the increased premiums in the commercial and Medicare markets that may result from the proposed change.

One commenter expressed that the proposed change will be doubly punitive to its state residents because as part of the state's market stabilization efforts, residents are subjected to a penalty for not carrying insurance. Additionally, the commenter noted that states that developed section 1332 waivers will be unduly penalized by this change because it will result in a reduction of premium tax credits. Another commenter noted that if more states implement section 1332 waivers, then a premium adjustment percentage that incorporates individual market premium changes would also reflect the impact of these waivers (that is, reduced individual market premiums) and could result in additional federal expenditures on premium tax credits through reduced required contributions. The commenter noted there could be challenges for states seeking new waivers to reflect the impact of this consideration when evaluating compliance with the deficit neutrality guardrail and the available amount of federal pass-through funding in their waiver applications.

Response: We believe that section 1302(c)(4) of the PPACA provides the Secretary of HHS with the authority to update and modify the premium adjustment percentage and premium growth rate measure, and that our proposal was within this authority. While we recognize that any reductions to federal PTC spending could reduce the pass-through amounts that are available to states that implement State Relief and Empowerment Waivers under section 1332 of the PPACA, those reductions in pass-through payments would be consistent with the reduction in the federal savings attributable to such waivers. Additionally, as noted in the regulatory impact section of this rule, we are aware that, if adopted by the Department of the Treasury and the IRS, this change in premium measures will likely have the effect of raising premiums, and we understand that such increases could have additional consequences for consumers in states where they may be penalized for not

carrying insurance. As explained in responses to other comments on this proposal, we believe these impacts are outweighed by the goals of achieving comprehensive and accurate calculations of premium growth. We will continue to consider possibilities for appropriate modifications to the calculation of the premium adjustment percentage that reflect the changing health insurance markets, and we will consider these and other comments as we develop future policy in this area.

Based on the final 2020 premium adjustment percentage, we are finalizing the following cost-sharing parameters for benefit year 2020.

Maximum Annual Limitation on Cost Sharing for Plan Year 2020

Under § 156.130(a)(2), for the 2020 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 2020. 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.

In the proposed rule, we proposed that the 2020 maximum annual limitation on cost sharing would be \$8,200 for self-only coverage and \$16,400 for other than self-only coverage, based on the previously proposed premium adjustment percentage of 1.2969721275 for 2020, 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, 2013.¹⁷⁹ As stated in this rule, we are finalizing the change in premium measure used to calculate the premium adjustment percentage as proposed, and thus the final premium adjustment percentage for the 2020 benefit year is 1.2895211380. Based on this premium adjustment percentage, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, the final 2020 maximum annual limitation on cost sharing will be \$8,150 for self-only coverage ($\$6,350 * 1.2895211380 = \$8,188.46$; rounded down to the next lowest multiple of 50 dollars is \$8,150) and \$16,300 ($\$8,150 * 2$) for other than self-only coverage. This represents an approximately 3.16 percent increase above the 2019 parameters of \$7,900 for self-only coverage and \$15,800 for other than self-only coverage.

¹⁷⁹ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

Comment: Several commenters expressed opposition to the increased maximum annual limitation on cost-sharing. Many commenters stated that they oppose the proposed change in premium measure for the premium adjustment percentage in part because of the effect it would have of further increasing the maximum annual limitation on cost-sharing for individuals and families. Multiple commenters suggested that if the premium adjustment percentage is not finalized as proposed, given the timing of the final rule, issuers should be allowed a safe harbor to use the proposed maximum annual limitation on cost-sharing for 2020. One commenter requested HHS lower the burden of out-of-pocket costs for patients or keep current cost-sharing limits at 2019 levels. Another commenter supported the flexibility to increase the out-of-pocket maximum to a higher limit and requested that HHS coordinate with the IRS in setting the maximum out-of-pocket limits for HSA-eligible HDHPs so they match.

Response: We recognize commenters' concerns about the burden that an increase in the maximum annual limitation on cost-sharing places on consumers who meet the annual limit. However, the indexing of this parameter is required under section 1302(c)(1)(B) of the PPACA, and does not permit HHS to postpone updates to these parameters for the applicable benefit year. Therefore, we are finalizing the 2020 maximum annual limitation on cost sharing of \$8,150 for self-only coverage and \$16,300 for other than self-only coverage, based on the premium adjustment percentage for the 2020 benefit year that is finalized in this rule. With regard to the maximum out-of-pocket limit that applies for purposes of HSA-eligible HDHPs, annual adjustments are determined under section 223(g) of the Code, which by statute provides a different annual adjustment than the annual adjustment provided under section 1302(c) of PPACA. Further, we note that the Department of the Treasury and the IRS have jurisdiction over HSAs and HSA-eligible HDHPs under section 223 of the Code.

f. 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 that change how the cost sharing required under the QHP is to be shared between the enrollee and the federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver-plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the PPACA, section 1402(c)(1)(B)(ii) states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AV of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee). Accordingly, we proposed to continue to use the 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 discussed in this rule, the finalized 2020 maximum annual limitation on cost sharing will be \$8,150 for self-only coverage and \$16,300 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. In this rule, we describe our analysis for the 2020 plan year and our proposed results.

Consistent with our analysis in the Payment Notices for 2014 through 2019, we developed three test silver-level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to the proposed estimated 2020 maximum annual limitation on cost

sharing for self-only coverage (\$8,200). The test plan designs are based on data collected for 2019 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 2020, the test silver-level QHPs included a PPO with typical cost-sharing structure (\$8,200 annual limitation on cost sharing, \$2,575 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, \$3,500 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$8,200 annual limitation on cost sharing, \$4,300 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 2020 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 of FPL (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (2/3 reduction), will 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 (1/2 reduction), will 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 with a

household income between 200 and 250 percent of FPL be reduced by approximately 1/5, rather than 1/2, consistent with the approach taken for benefit years 2017 through 2019. We further proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of FPL be reduced by approximately 2/3, as specified in the statute, and as shown in Table 9. 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 test 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 will not reduce the benefit afforded to enrollees in the 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 tested again using the numbers based on the final premium adjustment percentage, which are reflected below, and arrived at the same conclusions. We are therefore not considering any changes to the level of the reductions at this time.

In prior years we found, and we continue to find, that for individuals with household incomes of 250 to 400 percent of 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 in the statute. 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 of FPL.

We note that for 2020, 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. No state submitted a dataset by the September 1, 2018 deadline.

TABLE 9—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2020

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2020	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2020
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (100–150 percent of FPL)	\$2,700	\$5,400
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (151–200 percent of FPL)	2,700	5,400
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (201–250 percent of FPL)	6,500	13,000

Comment: One commenter noted that the proposal to reduce the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of FPL by approximately $\frac{1}{5}$, rather than $\frac{1}{2}$, consistent with the approach taken for benefit years 2017 through 2019, hurts their members. The commenter recommended that HHS rescind its plan to go through with these regulatory changes and asks that the Administration continue to support legislation to appropriate CSR funding.

Response: We share the commenter's concern about the impact of a smaller reduction in cost-sharing on individuals with a household income between 200–250 percent of FPL. We will continue to monitor plan AV and benefit design in future years for impact on premiums and out-of-pocket costs. We are finalizing the reductions with modifications to reflect the final premium adjustment percentage and maximum annual limitation on cost-sharing.

g. Application to Cost-Sharing Requirements and Annual and Lifetime Dollar Limitations (§ 156.130)

We proposed several policy changes to cost-sharing requirements, including a policy change as to what is included as EHB, which would affect the annual out-of-pocket limitation under PHS Act section 2707(b) and the annual and lifetime dollar limit prohibition under PHS Act section 2711. Although large group market coverage and self-insured group health plans are not required to cover all EHB, non-grandfathered group health plans and health insurance issuers are subject to PHS Act section 2707(b), and all group health plans and group health insurance issuers are subject to PHS Act section 2711, which are incorporated by reference in the Employee Retirement Income Security Act of 1974 (ERISA) and the Code.¹⁸⁰ To comply with those sections, such plans and issuers must choose a definition of EHB to determine which benefits are subject to the annual out-of-pocket limitation and the prohibition on lifetime and annual dollar limits.¹⁸¹

¹⁸⁰ Sections 2707(b) and 2711 of the PHS Act apply the annual cost-sharing limitation on EHBs and the prohibition on annual dollar limits on EHBs to non-grandfathered non-federal governmental group health plans of all sizes, and by implication, to large group health insurance issuers through which such plan provide coverage. Additionally, section 715 of ERISA and section 9815 of the Code incorporate those provisions by reference, applying them to non-grandfathered privately sponsored group health plans and their health insurance issuers in the small and large group markets.

¹⁸¹ Generally, for this purpose, a group health plan or health insurance issuer that is not required

Therefore, these proposals were relevant to, and would apply to, all health coverage and plans.

i. Cost-Sharing Requirements for Generic Drugs

In 2014, the Departments of Labor, HHS, and the Treasury¹⁸² (the tri-departments) released an FAQ on the treatment by large group market health insurance issuers and self-insured group health plans, with regard to the annual out-of-pocket limitation, of an individual's out-of-pocket costs for a brand drug when a generic equivalent is available and medically appropriate. Because large group market health insurance issuers and self-insured group health plans are not required to offer EHB, the FAQ states that such plans may include only generic drugs, if medically appropriate (as determined by the individual's personal physician) and available as EHB, while providing a separate option (not as part of EHB) of selecting a brand drug at a higher cost-sharing amount, as non-EHB. Thus, such plans could choose not to count toward the annual limit on cost sharing some or all of the amounts paid toward the brand drugs that are not EHB, if the participant or beneficiary selects a brand name prescription drug in circumstances in which a generic was available and medically appropriate (as determined by the individual's personal physician).¹⁸³

The FAQ also states that for non-grandfathered health plans in the individual and small group markets that must provide coverage of EHB, additional requirements apply.¹⁸⁴ This

to provide EHB must define such benefits in a manner that is consistent with—(1) one of the EHB-benchmark plans applicable in a state under § 156.110, and including any additional required benefits that are considered EHB under § 155.170(a)(2) or (2) one of the three Federal Employees Health Benefits Program plan options as defined by § 156.100(a)(3), supplemented, as necessary, to meet the standards in § 156.110. For more information regarding the application of the PHS Act section 2711 to group health plans and issuers, see the Departments implementing regulations at 26 CFR 54.9815–2711, 29 CFR 2590.715–2711, and § 147.126.

¹⁸² FAQs About Affordable Care Act Implementation (Part XIX). May 2, 2014. Available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html. This FAQ remains in effect for large group market and self-insured group health plans despite the fact that the related proposed policy for the individual and small group markets is not being finalized.

¹⁸³ In determining whether a generic is medically appropriate, the FAQ provides that a plan may use a reasonable exception process. For example, the plan may defer to the recommendation of an individual's personal physician, or it may offer an exceptions process meeting the requirements of § 156.122(c).

¹⁸⁴ For example, these plans have to meet the EHB drug count standard at § 156.122(a) that sets

reflects the implementation of the EHB requirements as implemented in the Patient Protection and Affordable Care Act (PPACA); Standards Related to Essential Health Benefits, Actuarial Value and Accreditation; Final Rule (EHB Final Rule),¹⁸⁵ in which we stated that plans are permitted to go beyond the number of drugs offered by the EHB-benchmark plan without exceeding EHB. We further clarified in the 2016 Payment Notice that, if the plan is covering drugs beyond the number of drugs covered by the EHB-benchmark plan, all of these drugs are EHB and cost sharing paid for the drugs must count toward the annual limitation on cost sharing.¹⁸⁶

Given the increase in the cost of prescription drugs, and particularly brand drugs, in the proposed rule, we stated that HHS believes additional flexibility is needed for health plans in the individual and small group markets that must provide coverage of the EHB to encourage consumers to use more cost effective generic drugs. We proposed, subject to applicable state law, to allow a plan that covers both a brand prescription drug and its generic equivalent, for plan years beginning on or after January 1, 2020, to consider the brand drug to not be EHB, if the generic drug is available and medically appropriate for the enrollee, unless coverage of the brand drug is determined to be required under an exception process at § 156.122(c).

Under such circumstances, if an enrollee purchases the brand drug when the generic equivalent was available and medically appropriate, we proposed that the issuer would be permitted to not count the difference in cost sharing between that which is paid for the brand drug and that which would be paid for the generic equivalent drug toward the annual limitation on cost sharing under § 156.130, but would still be required to attribute the cost sharing that would have been paid for the generic equivalent toward the annual limitation on cost sharing under § 156.130. This would maintain a balance between incentivizing the use of lower-cost drugs and the consumer protection provided by the annual limitation on cost sharing.

We further proposed that for a plan to do so, the plan must have an exception process in place in accordance with § 156.122(c) for the enrollee to request coverage of the brand drug.

a minimum threshold for drug coverage and while the drug count standard is based on chemically distinct drugs, these plans have to consider other factors in establishing their prescription drug benefit.

¹⁸⁵ 78 FR 12834, 12845 (February 25, 2013).

¹⁸⁶ 80 FR 10817.

If finalized, this interpretation would have permitted all group health plans and group health insurance issuers to impose lifetime and annual dollar limits on such brand drugs because they would no longer be considered EHB and not be subject to the prohibition on such limits.

HHS also considered an alternate proposal, under which an issuer would have been permitted to except the entire amount paid by a patient for a brand drug for which there is a medically appropriate generic alternative from the annual limitation on cost sharing at § 156.130. Because this alternate proposal also relied on an interpretation of what is considered EHB, the alternate proposal would have also applied to non-grandfathered group health plans and health insurance issuers subject to the annual limit on cost-sharing provision under PHS Act 2707(b), and in ERISA section 715 and Code section 9815.

We proposed that these changes to the annual limitations on cost sharing would be effective starting with the 2020 plan year. We solicited comments on these alternatives, both of which we proposed to apply to group health plans, group health insurance coverage, and individual market coverage, regardless of whether they are required to cover EHBs.

An issuer taking advantage of this proposed flexibility would be excluding the brand drug from coverage as EHB. Therefore, the issuer also could have imposed annual or lifetime dollar limits on coverage of the brand drug under those circumstances. Additionally, PTC (and APTC) could not be applied to any portion of the premium attributable to coverage of brand name drugs not covered as EHB, so issuers of QHPs would be required to calculate that portion of QHPs' premiums and report it to the applicable Exchange.

We also solicited comments on any limitation on group health plans' and health insurance issuers' information technology systems being able to accumulate the cost sharing consistent with this policy, whether this proposed policy should be subject to or preempt any state law regarding the application of cost sharing between the generic and branded version of a drug that would prevent the application of this proposed policy, and whether an issuer not attributing cost-sharing to the annual limitation on cost sharing under this approach should be considered an adverse coverage determination and subject to the coverage appeals processes under § 147.136.

Finally, we sought comment regarding whether we should *require*, instead of

permit, issuers to exclude brand drugs from being EHB if the generic drug is available and medically appropriate for the enrollee, unless coverage of the brand drug is determined to be required under the exception process under 156.122(c), and to exclude the cost sharing for the brand name drug from accumulating toward the annual limitation on cost sharing according to one of the proposed alternatives.

Comment: A few commenters supported the policy as proposed. Several commenters suggested that we not finalize this policy due to the administrative cost and burden of implementing the policy, and the potentially harmful consequences for those with chronic medical conditions. Several commenters also expressed concern about being able to implement the policy for the 2020 plan year. Many commenters noted the proposal would increase out-of-pocket expenses for enrollees. Some commenters expressed concern regarding the policies' impact on actuarial values, which are based on EHB for certain plans. Other commenters were not in favor of the alternative proposal due to the complexity and administrative burden of determining cost sharing under the proposal. Commenters also stated that plans and issuers already encourage enrollees to use generic drugs, and that the proposed policy is unnecessary and undermines the definition of EHB. There were several comments requesting clarification of the term "generic drug." A few commenters stated that the proposed policy should be optional for issuers.

Response: In light of commenters' concerns about the complexity of implementing this proposal, we are not finalizing this proposal at this time, and will continue to review the points raised by commenters.

ii. Cost-Sharing Requirements and Drug Manufacturers' Coupons

Drug manufacturers often offer coupons to patients to reduce patient out-of-pocket costs. Drug manufacturers may offer these coupons for various reasons: To compete with another brand name drug in the same therapeutic class, to compete with a generic equivalent when released, or to assist consumers whose drug costs would otherwise be extremely high due to a rare or costly condition.¹⁸⁷ Some states

prohibit the use of such coupons if a generic alternative is available.¹⁸⁸

We recognize that copayment support may help beneficiaries by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients. However, the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices which can distort the market and the true costs of drugs. Such coupons can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost effective drugs.

The Administration has identified high and rising out-of-pocket costs for prescription drugs, among other issues, as a challenge to consumers. In some cases, manufacturer coupons may be increasing overall drug costs and can lead to unnecessary spending by issuers, which is passed on to all patients in the form of increased premiums and reduced coverage of other potentially useful health care interventions. While the PPACA does not speak directly to the accounting and use of drug manufacturer coupons to the annual limitation on cost sharing, we believe that the overall intent of the law was to establish annual limitations on cost sharing that reflect the actual costs that are paid by the enrollee. The proliferation of drug coupons supports higher cost brand drugs when generic alternatives are available which in turn supports higher drug prices and increased costs to all Americans and for other federal health programs.

For these reasons, at new § 156.130(h)(2), we proposed, for plan years beginning on or after January 1, 2020, notwithstanding any other provision of the annual limitation on cost sharing regulation, that amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent are not required to be counted toward the annual limitation on cost sharing. Not counting such amounts toward the annual limitation

¹⁸⁷ Van Nuys, K., Joyce, G., Ribero, R., & Goldman, D.P. (2018). A Perspective on Prescription Drug Copayment Coupons. Los Angeles, CA: Leonard D. Schaeffer Center for Health Policy & Economics.

¹⁸⁸ For example, see, <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXIII/Chapter175H/Section3>.

on cost sharing would promote: (1) Prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market.

We noted that this proposal, which is permissive, would also apply to non-grandfathered group health plans, to which the annual out-of-pocket limitation applies under PHS Act section 2707(b) as incorporated into the Code and ERISA.

We sought comment on this proposal and whether states should be able to decide how coupons are treated. Additionally, we sought comment on whether it would be difficult for issuers to carve out direct support offered by drug manufacturers from their calculation of enrollees' payments toward their annual limitation on cost sharing, and to carve out exceptions (for when a generic equivalent is not available, for example), when cost sharing paid by direct support offered by drug manufacturers will be counted toward the annual limitation on cost sharing, including whether information technology systems could be easily updated for this purpose. We also sought comment on issuers' ability to differentiate between drug manufacturer coupons and other drug coupons, whether their information technology systems would need modifications to make such differentiation, what a reasonable implementation date would be if implementation barriers exist, and how drug discount programs (as opposed to coupons) should be treated under this proposal. Finally, we sought comment regarding whether this policy should be limited to QHPs only.

We are finalizing the policy as proposed, subject to the modifications discussed in the following responses to comments and a non-substantive grammatical correction. In addition, for consistency with the terminology currently used in § 156.130, we are making a non-substantive modification to the finalized regulatory text from "insured patients" to "enrollees". This modification is not intended to reflect a change in policy. Under this final rule, issuers are permitted to utilize this policy only to the extent permissible by applicable state law.

Comment: Many commenters supported HHS' proposal. Some commenters recommended that all manufacturer support for cost sharing that is provided directly to the patient be excluded from the annual limitation on cost sharing, not just for brand drugs where generic equivalents are available. Several commenters recommended that HHS update the policy so that enrollees

who indicate they may need a brand-name drug qualify for the appeals process in § 147.136 or the drug exception process under § 156.122(c). These commenters stated that if enrollees are found to require a brand-name drug, the issuer should be required to count brand drug coupons for that enrollee toward their cost-sharing limits. Some commenters also noted that coupon and discount programs are not transparent and recommended that HHS should standardize them to make their financial aspects more visible to pharmacies and issuers for purposes of implementing this proposal.

Response: We appreciate the important considerations raised by commenters, in particular regarding the exclusion of all manufacturer support for cost sharing that is provided directly to the patients from the annual limitation on cost sharing. As noted in the proposed rule, this policy is intended to address the distortion in the market caused when consumers choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. Therefore, the final regulation limits the discretion to exclude manufacturer coupons from counting towards the annual limitation on cost sharing for specific prescription brand drugs that have a generic equivalent, as the availability of a coupon may cause physicians and patients to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. Where there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market. Similarly, when an enrollee is determined through an appeals process in § 147.136 or the drug exception process under § 156.122(c) to require a brand drug because the generic or other alternative may not be available or medically appropriate, the use of the manufacturer coupon would not disincentivize a less expensive choice. Therefore, under those circumstances, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers must be counted toward the annual limitation on cost sharing. We have added language to the regulation text to address this clarification.

We believe that standardizing drug manufacturer coupon and discount programs is outside the scope of this rulemaking. We will consider these and other comments as we develop future policy in this area.

Comment: Some commenters were concerned that explicitly allowing an issuer to not count certain third-party payments towards the annual limitation on cost sharing is contrary to the PPACA. They expressed concerns that the proposal would increase out-of-pocket costs for certain patients with serious conditions, make medically necessary medication less affordable and accessible for them, and jeopardize their health because they find it more difficult to adhere to their drug regimen.

Response: We recognize commenters' concerns about the burden associated with the exclusion of manufacturer coupons from counting towards the deductible and annual limitation on cost sharing for specific prescription brand drugs that have a generic equivalent. However, the availability of a coupon may cause physicians and patients to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative are available. Such coupons can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost effective drugs.

Comment: Some commenters requested that HHS clarify the term "generic equivalent." One commenter suggested the proposed rule be limited to situations where the generic drug is rated as a therapeutic equivalent to the branded drug under the FDA Orange Book. Another commenter stated that the term "generic equivalent" was too broad and failed to reference the FDA's process of testing and approving generic drugs for use by consumers.

Response: We intended our proposal to refer to the term "generic equivalent" under a commonly understood meaning. Generic drugs primarily are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA). Therefore, in response to comments, we are finalizing regulation text to define "generic" for this purpose by reference to the FDCA. This definition is consistent with the definition of generic used for the Medicare Prescription Drug Benefit.¹⁸⁹

Comment: Several commenters were concerned that these changes should be permissive, but not required for plans and issuers. They highlighted that issuers may have difficulty in identifying when a coupon is used by enrollees to purchase drugs at a retail pharmacy. It may take issuers time to implement operational systems to track use of coupons.

¹⁸⁹ 42 CFR 423.4.

Response: We recognize commenters' concerns that use of these coupons may be difficult to track. Under the regulation, issuers may, but are not required to, undertake the option to exclude manufacturer coupons from counting towards the annual limitation on cost sharing.

Comment: Several commenters noted that the final language should expressly provide that these limitations on coverage only apply to the extent consistent with state law.

Response: In response to comments, we clarify that the ability to exclude amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent from being counted toward the annual limitation on cost sharing is subject to applicable state law. This means that states can require that such amounts be counted toward the annual limit on cost sharing. We are modifying the final regulation text to state this explicitly.

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

At § 156.280(c)(3), we proposed that, beginning with plan year 2020, if a QHP issuer provides coverage of non-Hyde abortion services¹⁹⁰ in one or more QHPs, the QHP issuer must also offer at least one "mirror QHP" that omits coverage of non-Hyde abortion services throughout each service area in which it offers QHP coverage through the Exchange, to the extent permissible under state law. We proposed that a "mirror QHP" provide identical benefit coverage to one of the QHPs with non-Hyde abortion coverage, with the exception of the inclusion of the coverage of non-Hyde abortion services. We received over 25,000 comments on this proposal, and are in the process of reviewing them. As we are still reviewing the comments, we are not able to finalize this proposal in the timeframe necessary to ensure that issuers are able to implement such a change before the opening of the QHP certification application window for the

¹⁹⁰ The Hyde Amendment as currently in effect permits federal funds to be used for abortions only in the limited cases of rape, incest, or if a woman suffers from a life-threatening physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, as certified by a physician. It further prohibits the use of federal funds for health benefits coverage that includes coverage of abortions in instances beyond those limited circumstances. In this rule, those services falling outside the scope of the Hyde Amendment are "non-Hyde abortion services."

2020 benefit year. We may finalize it in a future rulemaking. If we finalize this provision in future rulemaking, it would not take effect sooner than the 2021 benefit year.

6. Quality Standards (§§ 156.1120, 156.1125, 156.1130)

Regulatory reform and reducing regulatory burden are high priorities for us. To lower health care costs, enhance patient care, and reduce the regulatory burden on the health care industry, including for health plan issuers and the providers who deliver services through their plans, in October 2017, we launched the Meaningful Measures Initiative.¹⁹¹ This initiative is one component of our agency-wide Patients Over Paperwork Initiative.¹⁹²

The Meaningful Measures Framework is a strategic tool for putting patients over paperwork by identifying the highest priority areas for quality measurement and quality improvement, to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. This initiative is a new approach to quality measures that will foster operational efficiencies that include decreasing data collection and reporting burden while focusing on quality measurement aligned with meaningful outcomes.

By including Meaningful Measures in our quality reporting and quality improvement programs such as the Quality Rating System, QHP Enrollee Experience Survey and the Quality Improvement Strategy, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We encourage QHP issuers to use performance measures aligned with the Meaningful Measures Initiative in fulfilling their certification requirement to implement a Quality Improvement Strategy that provides increased reimbursement or other market-based incentives for improving health outcomes of plan enrollees.

¹⁹¹ "Meaningful Measures Hub." May 5, 2018. Available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

¹⁹² Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html>.

In addition, we will continue to assess quality measures in our programs including the Quality Rating System and the QHP Enrollee Experience Survey, to ensure that we are using a parsimonious set of the most meaningful measures for patients, clinicians, and health plans in those quality programs. If we propose any changes or removal of measures, we will include those for public comment in the Annual Call Letter for the QRS and QHP Enrollee Survey,¹⁹³ as well as address potential changes to information collection requirements to comply with the Paperwork Reduction Act.

Comment: Several commenters supported quality standards across the Exchanges, as well as the Meaningful Measures initiative to help streamline measures across quality reporting and quality improvement programs. One commenter recommended the stratification of quality measures by race, ethnicity, language, socioeconomic status, sex, gender identity, sexual orientation, disability, and other demographic factors and that we prioritize the inclusion of disparities-sensitive and health equity measures in the Meaningful Measures areas across domains. Some commenters mentioned that quality activities, such as the Quality Rating System and the QHP Enrollee Survey, empower consumers, promote high value care and are critical functions of an Exchange. Some commenters urged transparency of both price and quality data to help consumers choose high quality care.

Response: We did not propose updates to the Quality Rating System, QHP Enrollee Survey or Quality Improvement System regulations in the proposed rule. We appreciate the comments and will take them into consideration as we continue implementing CMS quality reporting programs such as the Quality Rating System, QHP Enrollee Survey and Quality Improvement Strategy.

7. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

As described in the preamble to §§ 155.220, 155.221, and 155.415, we proposed significant changes to these regulations to streamline and consolidate the requirements applicable to all direct enrollment entities—both QHP issuers and web-brokers. To reflect these changes, we also proposed conforming changes in § 156.1230(a)(2)

¹⁹³ Final 2018 Call Letter for the QRS and QHP Enrollee Survey. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/2018-QRS-Call-Letter_July2018.pdf.

and (b). We proposed to amend § 156.1230(b) to add a new paragraph (b)(1) that will require issuers participating in direct enrollment to comply with the applicable requirements in § 155.221. We also proposed to delete and reserve paragraph (a)(2) of § 156.1230 to reduce redundancies in light of the proposed changes to § 155.415. We did not receive any comments specific to the proposed changes to § 156.1230 and are finalizing these changes as proposed. For a more thorough discussion of these changes, please see the preamble to §§ 155.220, 155.221, and 155.415.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 OMB for review and approval. This final rule

contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 11. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We 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.¹⁹⁴ Table 10 in this final rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor 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 10—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES *

Occupation title	Occupational code	Mean hourly wage (\$/hr.)	Fringe benefits and overhead (\$/hr.)	Adjusted hourly wage (\$/hr.)
All Occupations	00-0000	\$24.34	\$24.34	\$48.68

* Note that only the occupations related to the ICRs being finalized are included in the table.

B. ICRs Regarding Risk Adjustment Data Validation Exemptions (§ 153.630(g))

In this final rule, we are codifying § 153.630(g)(3), under which an issuer will be exempt from risk adjustment data validation, beginning with the 2018 benefit year of risk adjustment data validation, if an issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that the issuer meets certain requirements. To qualify for this exemption, the issuer must provide to HHS, in a manner and timeframe to be specified by HHS, an attestation that the issuer will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual who can legally and financially bind the issuer. To qualify for the exemption, an issuer also could not have been a positive error rate outlier in the prior benefit year's risk adjustment data validation. We continue to anticipate that fewer than 10 issuers will submit this information to HHS

annually. Under 5 CFR 1320.3(c)(4), this ICR will not be subject to the PRA, as it will affect fewer than 10 entities in a 12-month period.

We are finalizing the proposal to codify at § 153.630(g)(1) and (2) two exemptions for certain issuers from risk adjustment data validation that were finalized in the 2018 and 2019 Payment Notices. The reduction in burden for issuers who meet the criteria to be exempted under proposed § 153.630(g)(1) and (2) was estimated in those rules, and have been incorporated into OMB Control Number 0938-1155 (CMS-10401—"Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment). Codifying these policies as part of HHS regulations as finalized in this rulemaking will not affect current burden estimates.

C. ICRs Regarding Agent or Broker Termination and Web Broker Data Collection (§ 155.220)

We are finalizing the requirement at § 155.220(c)(4)(i)(A), for web-brokers to provide HHS a list of agents or brokers that by contract or other arrangement

use the web-broker's website to assist consumers with QHP selection or completion of the Exchange eligibility application, in a form and manner to be specified by HHS. Currently, § 155.220(c)(4)(i)(A) requires the provision of this information if requested by HHS. The burden on a web-broker to comply with this requirement is covered by the information collection currently approved under OMB control number 0938-1349 (CMS-10650—State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities).

We are finalizing the provision at § 155.220(g)(3)(ii), to allow HHS to immediately terminate an agent's or broker's agreement(s) with the FFEs for cause with notice if an agent or broker fails to comply with the requirement to maintain the appropriate licensure in every state in which the agent or broker actively assists consumers with enrolling in QHPs on the FFEs or SBE-FPs. An agent or broker whose agreement(s) with the FFEs are immediately terminated for cause under

¹⁹⁴ See May 2017 Bureau of Labor Statistics, Occupational Employment Statistics, National

Occupational Employment and Wage Estimates.

Available at https://www.bls.gov/oes/current/oes_nat.htm.

the new proposed paragraph (g)(3)(ii) will be able to request reconsideration under § 155.220(h). Although the process to request reconsideration imposes a small burden on agents or brokers subjected to terminations, we anticipate fewer than 10 terminations annually under this new authority. Under 5 CFR 1320.3(c)(4), this ICR will not be subject to the PRA as we anticipate it will affect fewer than 10 entities in a 12-month period.

We are finalizing the proposal at § 155.220(m)(3), that the Exchange may collect from a web-broker during its registration with the Exchange under § 155.220(d)(1) or at another time on an annual basis, in a form and manner specified by HHS, information sufficient to identify the individuals who comprise the entity's corporate leadership or ownership, as well as any corporate or business relationships with other entities that may seek to register with the FFE as a web-broker. We believe the burden on a web-broker to comply with these requirements is covered by the information collection currently approved under OMB control number 0938-1349 (CMS-10650—State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities). In the supporting statement for that information collection, we stated web-brokers will also be required to provide other documentation as requested in response to emerging compliance issues, for HHS to monitor compliance. The information we proposed to collect based on proposed § 155.220(m)(3) is the type of information we anticipated when we referenced other documentation in response to emerging compliance issues.

D. ICRs Regarding Direct Enrollment Entity Standardized Disclaimer (§ 155.221)

We are finalizing the proposed provision at § 155.221(b)(2) to require direct enrollment entities (both QHP issuers and web-brokers) to prominently display a standardized disclaimer, in the form and manner provided by HHS, to assist consumers in distinguishing between direct enrollment entity website pages that display QHPs and those that display non-QHPs during a single shopping experience. HHS will provide the exact text for this disclaimer and the language will not need to be customized. As described in the preamble, we will provide further information on the text and other display details for the standardized disclaimer in guidance. At that time, we will estimate the burden associated with this requirement, solicit public

comment, and request OMB approval in accordance with the PRA, as may be necessary.

E. ICRs Regarding Special Enrollment Periods (§ 155.420)

We are finalizing the proposed special enrollment period at § 155.420(d)(6)(v), which will be subject to pre-enrollment verification of eligibility for the FFEs. Where possible, the FFE makes every effort to verify an individual's eligibility for the applicable special enrollment period through automated electronic means instead of through an applicant's submission of documentation. Consistent with other special enrollment periods subject to pre-enrollment verification, individuals will be required to provide supporting documentation¹⁹⁵ within 30 days of plan selection.

We estimate an additional 4,700 consumers will submit documents annually to verify their eligibility to enroll through the proposed special enrollment period in the FFE, and that a consumer will, on average, spend approximately 1 hour gathering and submitting required documentation. Using the average hourly wage for all occupations (at an hourly rate of \$48.68), we estimate the opportunity cost to a consumer completing this task to be approximately \$48.68. We estimate the total annual burden on those consumers submitting documentation will be approximately 4,700 hours with an equivalent cost of approximately \$228,796.

We are revising the information collection currently approved under OMB control number 0938-1207 (CMS-10468—Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment) to account for this additional burden. SBEs that choose to operationalize the proposed special enrollment period are encouraged to follow the same approach for pre-enrollment verification of special enrollment period eligibility.

F. ICRs Regarding Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the amendment to § 155.605(e) will create additional costs on, or burdens to, the

Exchanges. We anticipate it will decrease burden on those consumers who, when applying for a hardship exemption, choose to apply for the exemption through the IRS for 2018, saving them approximately 16 minutes since they will not be required to complete the exemption application or submit supporting documentation. HHS will continue to process exemptions under current regulations for all SBEs that elect this option, and anticipates a decrease in the volume of exemptions processed.

Based on historical data of the exemptions program and anticipating a decrease in individuals applying for exemptions as a result of the Tax Cuts and Jobs Act that reduced to \$0 the individual shared responsibility payment for months beginning after December 31, 2018, we estimate that approximately 50,000 individuals will apply for a hardship exemption annually through the FFE.¹⁹⁶ We expect 60 percent of those individuals will apply for a hardship exemption through the IRS for 2018, totaling 30,000 requests.

We estimate that the annual reduction in burden for the expected 30,000 hardship exemptions through the IRS for 2018 will be approximately 8,100 hours. Using the average hourly wage for all occupations (at an hourly rate of \$48.68 per hour) we estimate that the annual reduction in cost for each consumer will be approximately \$13, and the annual cost reduction for all consumers applying for hardship exemptions through the IRS for 2018 will be approximately \$394,308.

We anticipate the burden will also be reduced for those consumers who currently apply through Connecticut.¹⁹⁷ Based on the population of Connecticut, we expect 330 consumers from that state will apply for a hardship exemption through the IRS for 2018, as opposed to through the state Exchange. We estimate that the annual reduction in burden for the 330 hardship exemptions through the IRS will be approximately 89 hours. Using the average hourly wage for all occupations (at an hourly rate of \$48.68 per hour) we estimate the annual reduction in cost for each consumer will be approximately \$13, and the annual cost reduction for all consumers in Connecticut applying for a hardship

¹⁹⁵ Consumer submitted documents currently accepted by the FFE for purposes of demonstrating prior coverage and verifying attested income are available at <https://www.healthcare.gov/help/prove-coverage-loss/> and <https://www.healthcare.gov/verify-information/documents-and-deadlines/>, respectively.

¹⁹⁶ Although the Tax Cuts and Jobs Act 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.

¹⁹⁷ HHS processes exemptions for all SBEs except Connecticut.

exemption through the IRS for 2018 will be approximately \$4,337.

We will revise the information collection currently approved under

OMB control number 0938–1190 (CMS–10466—Patient Protection and Affordable Care Act: Exchange

Functions Eligibility for Exemptions) to account for this burden reduction.

G. Summary of Annual Burden Estimates for Requirements

TABLE 11—NEW ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total cost (\$)
155.420(d)(6)(v)	0938–1207	4,700	4,700	1	4,700	\$48.68	\$228,796
Total	4,700	4,700	4,700	\$228,796

* There are no capital/maintenance costs associated with the information collection requirements contained in this final rule; therefore, we have removed the associated column from Table 11.

H. 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 collections discussed in this rule, please visit CMS’ website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential 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 final rule (CMS–9926–F), the ICR’s CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due May 28, 2019.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule finalizes standards related to the risk adjustment program for the 2020 benefit year, clarifications and improvements to the risk adjustment data validation program, as well as certain modifications that will promote transparency, innovation in the private sector, reduce burden on stakeholders, and improve program integrity. The Premium Stabilization Rule, previous Payment Notices, and final risk adjustment¹⁹⁸ rules provided details on the implementation of the

risk adjustment program, including the specific parameters applicable for the 2014, 2015, 2016, 2017, 2018, and 2019 benefit years. This final rule finalizes additional standards related to cost-sharing parameters; the Exchanges, including exemptions, eligibility and enrollment; calculation of the premium adjustment percentage; and FFE and SBE–FP user fees.

B. Overall Impact

We have examined the impacts of this final 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), 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).

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 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 final 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 final rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this final rule aim to ensure taxpayer money is more appropriately spent and that states have additional flexibility and control over their insurance markets. They will reduce regulatory burden, and reduce administrative costs for consumers and direct enrollment entities.

HHS anticipates that the provisions of this final rule will help further the HHS’ goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed

¹⁹⁸ Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (Dec. 10, 2018).

choices, that the insurance market offers choices, and that states have more control and flexibility over the operation and establishment of Exchanges. Affected entities such as direct enrollment entities, and QHP issuers will incur costs to comply with the proposed new provisions, for example, those related to direct enrollment; and states will incur costs if they choose to implement the new special enrollment period. 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 12 depicts an accounting statement summarizing HHS' 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 all benefits and costs of this final rule. The effects in Table 12 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers. The annualized monetized costs described in Table 12 reflect direct administrative costs and savings to health insurance issuers and consumers as a result of the provisions regarding special enrollment periods, use of direct enrollment entity application assisters to carry out responsibilities currently performed by agents or brokers, and applying for hardship exemptions. The annualized monetized transfers described in Table 12 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers, the potential increase in PTC for those qualifying individuals that use the new special enrollment period, and the potential decrease in PTC and increase in health insurance provider fees and employer shared responsibility payments due to the change in the premium adjustment percentage, and the corresponding changes the

Department of the Treasury and the IRS are expected to make with regard to their policies on calculating these parameters. We are finalizing the risk adjustment user fee of \$2.16 per billable member per year for the 2020 benefit year to operate the risk adjustment program on behalf of states,¹⁹⁹ which we estimate to cost approximately \$50 million in benefit year 2020. We expect risk adjustment user fee transfers from issuers to the federal government to increase by \$10 million, compared to the \$40 million estimated for the 2019 benefit year; this increase is included in Table 12. Additionally, we are finalizing an FFE user fee rate of 3.0 percent of premiums for the 2020 benefit year, which is lower than the 3.5 percent FFE user fee rate finalized for 2014 to 2019 benefit years. We are also finalizing an SBE-FP user fee rate of 2.5 percent of premiums for the 2020 benefit year, which is lower than the 3.0 percent SBE-FP user fee rate we finalized for the 2019 benefit year. Also, we are updating the premium adjustment percentage for the 2020 benefit year, resulting in a final premium adjustment percentage of 1.2895211380 percent.

TABLE 12—ACCOUNTING TABLE

Benefits:

Qualitative:

- Greater market stability resulting from updates to the risk adjustment methodology.
- Potential increased enrollment in the individual market stemming from lower premiums due to expansion of direct enrollment opportunities, 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.
- Greater continuity of coverage for consumers related to the special enrollment period.
- Reduced Navigator training compliance burden and increased flexibility in training design for Exchanges by streamlining the existing training topics into four broad categories.
- Reduced burden to FFE Navigators by making the duties listed at § 155.210(e)(9) permissible for FFE Navigators, not required.
- Strengthened program integrity related to agents and brokers and direct enrollment entities.
- Reduction in burden associated with risk adjustment data validation for issuers eligible for the liquidation exemption.
- Potential reduction in economic distortions, and improvement in economic efficiency as a result of the reduction in Exchange enrollment due to the change in the method of calculating the premium adjustment percentage.

Costs:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$/year)	-\$14.042	2018	7	2019–2023
	-\$14.037	2018	3	2019–2023

Quantitative:

- Costs incurred by issuers and consumers to comply with provisions related to special enrollment periods.
- Reduction in burden and costs for consumers applying for hardship exemptions through IRS.
- Reduction in burden and cost for direct enrollment entities that choose to use direct enrollment entity application assisters to carry out responsibilities currently performed by agents or brokers.
- Regulatory familiarization costs.

Qualitative:

- Costs to issuers due to increases in providing medical services if health insurance enrollment increases.
- Potential costs to Exchanges that opt to implement the special enrollment period for qualified individuals who experience a decrease in household income and are newly determined eligible for APTC, and to issuers for processing related enrollments and terminations.

¹⁹⁹ As noted earlier in this final rule, no state has elected to operate the risk adjustment program for

the 2020 benefit year; therefore, HHS will operate

the program for all 50 states and the District of Columbia.

TABLE 12—ACCOUNTING TABLE—Continued

Transfers:	Estimate (million)	Year Dollar	Discount Rate (percent)	Period Covered
Federal Annualized Monetized (\$/year)	\$954	2018	7	2019–2023
	\$976.6	2018	3	2019–2023

Quantitative:

- Transfer from health insurance issuers to the federal government of \$50 million as risk adjustment user fees for 2023 (the amount will increase by \$10 million from that previously estimated for 2020–2022).
- Transfer from federal government of \$15.3 million in premium tax credits to consumers enrolling through special enrollment period.
- Health Insurance Providers Fees of approximately \$50 million in 2020 and \$70 million per year between 2021 and 2023, which is a transfer from issuers to the federal government, and Employer Shared Responsibility Payments of \$100 million in 2020 and \$110 million per year between 2021 and 2023, which is a transfer from employers to the federal government.
- Reductions in federal premium tax credit spending of approximately \$980 million in 2020, \$1.04 billion in 2021, \$1.09 billion in 2022 and \$1.15 billion in 2023, which is a transfer from consumers to the federal government, due to the change in the method of calculating the premium adjustment percentage.
- Between 2020 and 2023, net premium increases of approximately 1 percent or \$181 million in additional net premiums per year, which is a transfer from consumers and the federal government to issuers.

Qualitative:

- The net effect on premiums is uncertain.
- Potential increase in federal and state uncompensated care costs as a result of lower Exchange enrollment due to the change in the method of calculating the premium adjustment percentage.

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 and temporary risk corridors programs ended after the 2016 benefit year. Therefore, the costs associated with those programs are not included in Tables 12 or 13 for fiscal years 2020–2023. Table 13 summarizes the effects of the risk adjustment program on the federal budget from

fiscal years 2019 through 2023, 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 risk adjustment program that is described in Table 13. 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 12).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on this internal analysis, we anticipate that the quantitative effects of the provisions in this final rule are consistent with our previous estimates in the 2019 Payment Notice for the impacts associated with the APTC, the premium stabilization programs, and FFE user fee requirements.

TABLE 13—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT PROGRAMS FROM FISCAL YEAR 2019–2023

[In billions of dollars]

Year	2019	2020	2021	2022	2023	2019–2023
Risk Adjustment Program Payments	5	6	6	6	7	30
Risk Adjustment Program Collections * ...	5	6	6	7	7	31

Note 1: Risk adjustment program payments and receipts lag by one quarter. Receipts 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: 2018 to 2028* Table 2. May 2018. Available at <https://www.cbo.gov/system/files?file=2018-06/51298-2018-05-healthinsurance.pdf>.

1. Risk Adjustment

The risk adjustment program is a permanent program created by section 1343 of the PPACA that collects charges from issuers with lower-than-average risk populations and uses those funds to make payments to issuers with higher-than-average risk populations in the individual, small group, and merged markets (as applicable), inside and outside the Exchanges. We established standards for the administration of the

risk adjustment program in subparts A, B, D, G, and H of 45 CFR part 153.

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. Consistent with § 153.610(f), 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 2020

benefit year, we estimated that the total cost for HHS to operate the risk adjustment program on behalf of all states will be approximately \$50 million, and that the risk adjustment user fee will be approximately \$2.16 per billable member per year, or \$0.18 PMPM. The updated cost estimates attribute all costs related to the EDGE server data collection and data evaluation (quantity and quality evaluations) activities to the risk adjustment program, rather than sharing

them with the reinsurance program, which is no longer operational. Previously, we had collected amounts for reinsurance administrative expenses, which partially funded contracts that were used for both the risk adjustment and reinsurance programs. Now, those costs are borne by the risk adjustment program alone. Additionally, based on experience with the risk adjustment data validation program's development and execution, including development of the new risk adjustment data validation audit tool and additional contractor support for processing risk adjustment data validation discrepancies and appeals, we estimate higher costs associated with the risk adjustment data validation program. Finally, we are incorporating the full amount of eligible personnel and administrative costs associated with risk adjustment program development and operations, including indirect costs, in the risk adjustment user fee for the 2020 benefit year. The personnel and administrative costs included in the calculation of the 2019 benefit year risk adjustment user fees in the 2019 Payment Notice final rule incorporated only a portion of the eligible personnel costs, and excluded indirect costs. Finally, we estimate similar billable member month enrollment for the 2020 benefit year as the most recent 2017 benefit year individual and small group market enrollment.

We believe that the approach of blending (or averaging) 3 years of separately solved coefficients from the 2016 and 2017 benefit year enrollee-level EDGE data with the 2015 MarketScan® data will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2019 benefit year to the 2020 benefit year due to differences in the datasets' underlying populations. Furthermore, we are finalizing the use of enrollee-level EDGE data and reports extracted from issuer EDGE servers to calibrate and operationalize HHS programs for the individual and small group (including merged) market programs, as well as to more broadly conduct policy analysis for the individual and small group (including merged) markets.

2. Risk Adjustment Data Validation (§ 153.630)

Under § 153.630, we proposed a few changes to the requirements for risk adjustment data validation.

We are finalizing the changes to the pairwise means test that will increase the second validation audit sample to the full 200 enrollee sample size (rather than 100) in certain cases. We do not

believe this policy will increase the burden on issuers because the second validation audit is conducted by HHS, not issuers, and issuers are already required to provide the initial and second validation audit entities with the documentation necessary to complete the audits for all 200 enrollees sampled. Instead, we believe that increasing the second validation audit sample size to the full initial validation sample of 200 enrollees, in certain cases, may increase the costs to the federal government of conducting the second validation audit, as HHS will now review the documentation submitted for all 200 enrollees, rather than only 100 in certain cases. However, we believe that the benefits from improving the process for validating the second validation audit results and the accompanying precision it will bring to risk score error rate adjustments will outweigh the increased costs to the federal government and better ensure the integrity of the risk adjustment program.

We are finalizing our proposal to incorporate prescription drugs into risk adjustment data validation as part of the data validation process. We believe that it is important that prescription drugs are validated as part of risk adjustment data validation, as the HHS-operated risk adjustment methodology started incorporating prescription drug factors beginning with the 2018 benefit year. HHS previously estimated the burden of incorporating drugs in risk adjustment data validation in the 2018 Payment Notice.

The exemptions in this final rule for risk adjustment data validation codify two policies finalized in the 2018 and 2019 Payment Notices and also include one new exemption policy for issuers in or entering liquidation. The impact of the previously finalized exemptions was addressed in the 2018 and 2019 Payment Notices. We believe that the number of issuers that will qualify for the exemption for issuers in liquidation will be very small each year, and therefore, we believe that the overall reduction in burden will be limited. However, those issuers that are exempted from risk adjustment data validation will have less burden and administrative costs than an issuer subject to these requirements.

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

In § 155.220(c)(3)(i), the new paragraph (c)(3)(i)(L) prohibits web-brokers from displaying QHP recommendations on their websites

based on compensation a web-broker, agent, or broker receives from QHP issuers. Web-brokers often collect certain information from consumers and on the basis of that information display or sort QHPs, or apply a score to all available QHPs, indicating which QHP they believe is the best option for those consumers. We support the development and use of innovative consumer-assistance tools that may help consumers select QHPs that best fit their needs. However, we believe such recommendations should be based on information consumers have provided to web-brokers and not based on compensation received from QHP issuers when consumers enroll in their plans. We are not aware of any web-brokers currently recommending QHPs based on compensation received from QHP issuers, so we expect the impact of this provision to be very limited.

We are finalizing the requirement in § 155.220(c)(4)(i)(A) for web-brokers to provide HHS with a list of agents or brokers who, through a contract or other arrangement, use the web-brokers' websites to assist consumers with QHP selection or completion of the Exchange eligibility application, in a form or manner to be specified by HHS. The authority currently exists for HHS to obtain this information by request. However, due to the trend of increased use and expansion of direct enrollment pathways, we believe it is appropriate and necessary to collect this information proactively, so that we may respond more efficiently and effectively to any potential instances of noncompliance that may involve use of a web-broker's direct enrollment pathway. Having this information will, for example, enable us to identify more quickly whether noncompliance is attributable to a specific individual or individuals, instead of the web-broker entity. We will release guidance that provides details on the form and manner of these submissions. We anticipate that it will require the list to include, at minimum, each agent's or broker's name, state(s) of licensure, and National Producer Number. We believe the burden associated with this data collection will be relatively limited, as we understand that web-brokers collect and store this information as part of their normal business operations to identify individual agents or brokers utilizing their systems. The burden related to this provision is discussed previously in the Collection of Information Requirements section.

Under new § 155.220(g)(3)(ii), HHS is allowed to immediately terminate an agent's or broker's agreement if the agent or broker fails to maintain

applicable state licensure as an agent, broker, or insurance producer in every state in which the agent or broker actively assists consumers with applying for APTC or CSRs or with enrolling in QHPs through the FFEs or SBE-FPs. State licensure for agents and brokers in every state in which they are assisting consumers is a fundamental consumer protection and critical for program integrity. It has been a requirement in the FFE agreements with agents and brokers since the inception of the FFEs, and is adhered to by the overwhelming majority of agents and brokers. Therefore, we believe the impact of this provision on agents and brokers will be minimal, but the proposal will benefit consumers who might otherwise interact with unlicensed individuals and will improve Exchange program integrity.

In § 155.220(k) a new paragraph (k)(3) is added that will allow HHS to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction. This language is identical to an existing provision that applies to web-brokers at § 155.220(c)(3)(i)(L) and a similar provision applicable to QHP issuers participating in direct enrollment at § 156.1230(b)(1). Those provisions are being replaced with a very similar new requirement that applies to both types of direct enrollment entities in new § 155.221(d). Because the potential risks posed by agents and brokers with access to FFE systems are similar to those posed by web-brokers and QHP issuers participating in direct enrollment, we believe this change is necessary and appropriate to provide a uniform process and ability to protect Exchange systems and operations from unacceptable risks, as well as to protect sensitive consumer data. We note that agents and brokers whose ability to transact information with the Exchange is suspended under this authority will remain registered and authorized to assist consumers using the Marketplace (or side-by-side) pathway, unless and until their agreements are suspended or terminated under § 155.220(f) or (g). We believe this authority will be used infrequently and only in cases where there will likely be the reasonable basis to suspend their agreements under § 155.220(g)(5)(i) but there is a need to take immediate action to protect sensitive consumer data or Exchange

systems and operations. Therefore its effect on agents and brokers is expected to be relatively limited.

In § 155.220(m)(1), we are finalizing the provision to allow a web-broker's agreement to be suspended or terminated for cause under § 155.220(g), and a web-broker to be denied the right to enter into agreements with the FFEs under paragraph (k)(1)(i) of this section based on the actions of its officers, employees, contractors, or agents, even if those persons are not agents or brokers registered with the FFE. In § 155.220(m)(2), we are finalizing the provision to allow a web-broker's agreement to be suspended or terminated under § 155.220(g), and for the entity to be denied the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), if it is under the common ownership or control, or is an affiliated business, of another web-broker that has had its agreement suspended or terminated for cause. We expect these provisions to have limited impact, as they are designed to protect program integrity and will only be utilized in limited cases when there is evidence of significant misconduct or non-compliance. In those cases, we anticipate benefits to consumers stemming from our enhanced ability to address program integrity concerns and non-compliance issues. In § 155.220(m)(3), we are finalizing the requirement for the Exchange to collect information from a web-broker sufficient to establish the identities of individuals who comprise its corporate leadership and to determine any business relationships with other entities that may seek to register with the Exchange as web-brokers. These provisions are also intended to protect program integrity by enabling the Exchange to have information necessary to determine if any individuals seeking to be web-brokers are attempting to circumvent a previous termination or suspension for cause of FFE agreements. The burden related to this provision is discussed in the Collection of Information Requirements section.

4. Direct Enrollment (§§ 155.20, 155.220, 155.221, 155.415, 156.1230)

The changes to § 155.220 are discussed above. In § 155.221, we amend and redesignate the existing paragraphs (a), (b) and (c) to new paragraphs (e), (f), and (g). In new § 155.220(e), we add language to require that the third-party entities that conduct annual reviews of direct enrollment entities to demonstrate operational readiness consistent with new

§ 155.221(b)(4)²⁰⁰ be independent of the entities they are auditing. We believe an independent audit is less likely to be influenced by a direct enrollment entity's business considerations, and therefore, is more reliable. We expect no impact from this provision as it was included as a requirement in the agreements we executed with direct enrollment entities subject to these audits for plan year 2019. We also clarify in § 155.221(e) that an initial audit is required, in addition to subsequent annual audits. This clarification does not represent a change from the current approach, as direct enrollment entities are currently required to demonstrate operational readiness before their websites may be used to complete QHP selections.²⁰¹ Therefore we anticipate no impact of this proposed change. In § 155.221(f), we require that a written agreement must be executed between a direct enrollment entity and its auditor stating that the auditor will comply with the requirements of paragraph (f). We believe the most effective way to ensure a direct enrollment entity has the necessary control and oversight over its auditor to ensure compliance with the applicable standards in § 155.221 is for those standards to be memorialized in a written agreement. We expect most, if not all, direct enrollment entities already execute written agreements with their contractors that will incorporate any regulatory requirements that fall within the scope of the work the contractor is performing for the entity, so we expect little to no impact from this change.

In the new § 155.221(a), we are codifying in regulation the types of entities the FFEs permit to offer non-Exchange websites to facilitate direct enrollment in coverage offered through the Exchange in a manner that is considered to be through the Exchange. There are two types of entities that are authorized by the FFEs to offer direct enrollment pathways: QHP issuers and web-brokers. We expect this provision to have little or no impact as QHP issuers and web-brokers are already authorized by the FFEs to participate in direct enrollment.

In the new § 155.221(b), we establish and consolidate certain requirements that apply to all direct enrollment entities. Specifically, we add in § 155.221(b)(1) that QHPs and non-

²⁰⁰ Direct enrollment operational readiness review requirements are currently captured at § 155.220(c)(3)(i)(K) for web-brokers and § 156.1230(b)(2) for QHP issuers.

²⁰¹ See § 156.1230(b)(2) for issuers participating in direct enrollment and § 155.220(c)(3)(i)(K) for web-brokers.

QHPs must be displayed and marketed on separate website pages on the direct enrollment entity's non-Exchange website. We consider this a clarification of existing standards that will have minimal impact on direct enrollment entities, and will minimize the chance that consumers are confused by the display or marketing of QHPs and non-QHPs on a single website page. In the new § 155.221(b)(2) we require the prominent display of a standardized disclaimer in a form and manner provided by HHS. Similar uniform disclaimer requirements already exist for all direct enrollment entities. As a result, and because we will provide the disclaimer text, we expect the overall impact of this provision to be minimal. In the new § 155.221(b)(3), we limit the marketing of non-QHPs during the Exchange eligibility application and QHP selection process on direct enrollment entities' websites in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. This will also assist consumers in understanding the applicability of APTC and CSRs that they may be eligible for. Most direct enrollment entities have refrained from marketing non-QHPs in conjunction with QHPs citing a lack of clear guidance on what was permissible. Therefore we expect the impact of this provision to be minimal, and to be perceived as allowing increased flexibility. In the new § 155.221(b)(4), we consolidate a provision requiring direct enrollment entities demonstrate operational readiness and compliance with applicable requirements prior to the entities' websites being used to complete an Exchange eligibility application or a QHP selection. Because this is an existing requirement, we expect no impact.

In the new § 155.221(c), the authority to use application assisters and the corresponding requirements when doing so apply for all issuers and direct enrollment entities and not solely QHP issuers. We are finalizing a new definition of "direct enrollment entity application assister" in § 155.20 that mirrors the existing definition of "issuer application assister", as well as finalizing amendments to § 155.415 to capture the requirements for entities using application assisters that align with the existing requirements currently in § 156.1230(a)(2) for QHP issuer application assisters. There is one significant deviation from the existing requirements for application assisters. Currently, § 156.1230(a)(2)(i) requires all application assisters to receive training

on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations. Licensed agents and brokers currently assisting consumers with QHP enrollment through the FFEs or SBE-FPs must have credentials to access FFE systems to offer that assistance. Those credentials are obtained during the FFE registration and training processes for agents and brokers. For application assisters to have similar access to FFE systems, so that they are also able to assist consumers as described here and in the preamble in this rule, they will need credentials similar to those obtained by agents and brokers during FFE registration and training. Therefore, we require that application assisters providing assistance in the FFEs and SBE-FPs comply with this training requirement by completing a similar registration and training process, in a form and manner to be specified by HHS, so that they will have the necessary credentials to provide consumer assistance. This new training and registration requirement for application assisters is captured in the new § 155.415(b)(1). The burden placed on application assisters to complete the FFE training may exceed what may have otherwise existed if direct enrollment entities were developing and managing their own training programs. However, by requiring the FFE training to be completed by application assisters assisting consumers in the FFEs and SBE-FPs, it will relieve direct enrollment entities from the burdens associated with having to develop and manage their own training programs. Importantly, FFE systems will require this approach to comply with system security requirements and to enable application assisters to meaningfully be able to assist consumers in the FFEs and SBE-FPs. Therefore, taken together, we believe the net burden associated with this requirement will be minimal and will be acceptable to participating direct enrollment entities that elect to use application assisters, when permitted under state law. The reason we believe the net burden will be minimal is because the bulk of time associated with application assisters completing the training requirement will likely be comparable whether the training is developed and administered by direct enrollment entities or by HHS. However, there will likely be a small increase in the amount of time application assisters will have to devote to the registration process apart from training, specifically to creating an FFE account and completing identity proofing. In contrast, there will likely be

a substantial reduction in burden on direct enrollment entities, because they will not have to develop and manage their own training programs. Instead they will be able to simply confirm their application assisters have completed the FFE registration and training process.

We anticipate that allowing QHP issuers to use application assisters in the FFEs and SBE-FPs, and expanding that option to other issuers and web-brokers will provide cost savings to these entities. It is difficult to precisely estimate the number of applications for which a direct enrollment entity application assister provided help may be submitted. However, based on available data, we estimate that approximately 980,000 agent or broker-assisted direct enrollment applications will be submitted in plan year 2019. We estimate that it will take an insurance sales agent²⁰² (at an hourly rate of \$64.42) one hour to complete an application. We do not have information related to the number of states that will allow for unlicensed application assisters, as well as how many direct enrollment entities will hire application assisters or train existing staff as application assisters. Therefore, we estimate that half of assisted direct enrollment applications will be completed with the assistance of an application assister instead of an agent or broker. Based on these assumptions, we estimate that it will take an insurance claims and policy processing clerk²⁰³ (at an hourly rate of \$39.52) one hour to complete each application. Thus, we estimate that the applications for 490,000 applicants will result in an estimated total burden of approximately 490,000 hours with an associated cost of approximately \$19,364,800. If the applications are completed by an agent or broker instead, the total cost will be approximately \$31,565,800. Based on these assumptions, we estimate an overall annual savings of approximately \$12.2 million for direct enrollment entities using application assisters instead of only agents or brokers. In addition, we expect that the time that agents or brokers may otherwise have spent assisting consumers with their eligibility applications will often instead be devoted to assisting more consumers with plan selection and finalizing their enrollments. As a result, we expect this policy may also result in an overall increase in enrollment

²⁰² Bureau of Labor Statistics mean hourly wage for an Insurance Sales Agent (Occupational Code 41-3021) at \$32.21 an hour, plus 100 percent fringe.

²⁰³ Bureau of Labor Statistics mean hourly wage for an Insurance Claims and Policy Processing Clerk (Occupational Code 43-9041) at \$19.76 an hour, plus 100 percent fringe.

through the FFEs and SBE-FPs. Lastly, these provisions provide increased flexibility and a level playing field to all direct enrollment entities and issuers.

In the new § 155.221(d), we consolidate existing authority to immediately suspend a direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the Exchange's ability to make accurate eligibility determinations, or Exchange operations or systems until such circumstances are remedied or sufficiently mitigated to HHS' satisfaction. We expect little or no impact from this proposal, since this is largely based on an existing authority.

We also codify new definitions for the following terms in § 155.20: "direct enrollment entity", "direct enrollment technology provider", and "web-broker". We define "direct enrollment entity" as an entity that an Exchange permits to assist consumers with direct enrollment in QHPs offered through an Exchange in a manner considered to be through the Exchange as authorized by §§ 155.220(c)(3), 155.221, or 156.1230. We expect no impact from this provision as it merely codifies a definition for the term in such a way that the entities that are currently authorized by the FFE to host a direct enrollment environment are direct enrollment entities. We also amend § 155.20 to define "direct enrollment technology provider" as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker, to provide technology services to facilitate participation in direct enrollment as a web-broker in accordance with §§ 155.220(c)(3) and 155.221. There may be instances when an individual agent or broker, a group of agents or brokers, or an agent or broker business entity engages the services of or creates a technology company that is not licensed as an agent or broker to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. In such cases, when the technology company is not itself licensed as an insurance agency or brokerage, these technology companies will be considered a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless noted otherwise. We expect no new burden associated with this requirement as it merely allows some flexibility in

terms of how licensed agents or brokers may organize their businesses or pursue business relationships when seeking to become web-brokers. We also codify a definition of "web-broker" as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. As explained in the preamble, we also define the term "web-broker" to generally include direct enrollment technology providers. Importantly, this definition will replace HHS' current web-broker definition, which is slightly different. However, we expect no impact, because all existing web-brokers will fall within the new proposed definition of web-broker.

Conforming edits were also made to § 156.1230 as part of the effort to streamline and consolidate similar requirements that apply to all direct enrollment entities in one regulation. We amend § 156.1230(b) to add a new paragraph (b)(1) that requires issuers participating in direct enrollment to comply with the applicable requirements in § 155.221. There were minimal substantive changes to the underlying requirements applicable to issuers participating in direct enrollment. We therefore expect no new impact to issuers except to the extent previously discussed. We also delete and reserve § 156.1230(a)(2) to align with the changes, described in this rule, to § 155.415 regarding application assisters.

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

Since implementing the direct-to-issuer enrollment system in plan year 2018, we have seen a marked decrease (greater than fifty percent) in the volume of SHOP Call Center calls. We anticipate that the SHOP Call Center volume will continue to decrease in plan year 2020, as employers will be in the third year of enrolling in SHOP directly with issuers, often with the assistance of agents and brokers. In addition, agents and brokers and small employers can now resolve most issues directly with impacted issuers using well-established issuer call centers and small group processes unique to each market. We anticipate a minimal number of new appeals of SHOP eligibility and special enrollment periods given anticipated employer participation and our observation that very few employers ever appeal SHOP determinations.

In short, we will maintain a toll-free telephone hotline that the statute requires (at present 12 full-time equivalent employees are devoted to SHOP Call Center operations). We envision minimal contractor and staff support to maintain the hotline content and to respond to very few voicemail messages. Although we will maintain language translation service and incur the associated costs, we anticipate that such costs will be minimal given call volume. Moving to an interactive voice response system will eliminate staffing for 12 full-time equivalent employees required at the call center under the SHOP Plan Aggregate and Call Center contract and will provide a net savings to the government of approximately \$2 million annually.

6. Navigator Program Standards (§§ 155.210 and 155.215)

We provide more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible for FFE Navigators, not required. The amendment of § 155.210 to remove the requirement that Navigators in FFEs provide the assistance specified at § 155.210(e)(9) will reduce regulatory burden and allow FFE Navigators to better prioritize work according to consumer demand, community needs, and organizational resources. Under the provision, Navigators in FFEs may continue to provide the types of assistance listed at § 155.210(e)(9), but will not be required to do so.

The time FFE Navigators currently spend providing assistance with the § 155.210(e)(9) topics varies. To help quantify this burden reduction, we requested comment on how many hours per month FFE Navigator grantees and individual Navigators currently spend providing the assistance activities in § 155.210(e)(9), what percentage of their current work involves providing these types of assistance, and how that amount of work would be impacted if providing these types of assistance would no longer be required. We also requested comment on how Navigator grantees and individual Navigators might reprioritize work and spend time fulfilling their other duties, if not required to provide the types of assistance described under § 155.210(e)(9). In particular, we sought comment on what tasks Navigators might prioritize and complete during the time they otherwise might have provided these types of assistance.

Commenters stated that the amount of time Navigators reported that they spent providing post-enrollment assistance varied widely. One commenter stated

that a broad range of post-enrollment activities were among the most common areas of assistance requested by consumers. Another commented that while they did not spend much time on tax processes, forms, appeals, or exemptions, the time they spent educating consumers about basic health concepts and how to use their health coverage was extensive. Another commented that, on average, Navigators visited each enrolled consumer ten times, and that three of those visits were dedicated to providing post-enrollment assistance. Another commenter stated that one of their Navigators spent 6 months and more than 40 hours helping a consumer file an appeal.

We amend Navigator training requirements at §§ 155.210(b)(2) and 155.215(b)(2) to provide greater flexibility to Exchanges in designing their Navigator training programs to ensure coverage of the most instructive and timely topics in a streamlined fashion and to align the training with future changes in the Navigator program or the operation of the Exchanges, while still ensuring that Navigators are qualified to carry out their activities as required by the Navigator statute and regulations. This additional flexibility will allow Exchanges to focus on training areas they determine to be most relevant to the populations in the Exchange service area, while still addressing all required or authorized Navigator functions. Because it will provide greater flexibility to tailor the training to current, local conditions in each Exchange, the revised approach might also help to ensure cost-effective use of Exchange Navigator funding.

Moreover, we believe these changes will also grant greater flexibility to SBEs, including SBE-FPs, in designing their respective Navigator training, since SBEs that decide to authorize or require their Navigators to provide the assistance specified under § 155.210(e)(9) will not have corresponding training topics prescribed, but will have the flexibility to decide how best to prepare their Navigators to provide such assistance. This is similar to the flexibility SBEs have for creating training for other required Navigator duties. We believe granting SBEs the flexibility to focus on the topics they find best suited to prepare their Navigators for assisting consumers will allow for a more effective training program, and will reduce the regulatory compliance burden on these Exchanges.

However, the burden reduction that this will achieve cannot be estimated since these changes are not intended to reduce the total number of hours of

Navigator training annually and we are uncertain how each Exchange will choose to structure its respective Navigator training given this increase in flexibility. We continue to believe that each Exchange is in the best position to determine the training that is most appropriate for the activities of its Navigators.

7. Special Enrollment Periods (§ 155.420)

We anticipate that amended § 155.420 will impose moderate costs on Exchanges that opt to implement the proposed special enrollment period to update their user interfaces and make changes to their eligibility systems, but also acknowledge that Exchanges may choose to offer the special enrollment period through their call center or other existing enrollment avenues that could greatly reduce implementation costs to an Exchange. Additionally, we anticipate that verification requirements will impose costs relating to special enrollment period pre-enrollment verification systems, caseloads, and consumer messaging for Exchanges that perform pre-enrollment verification of special enrollment period eligibility. We expect utilization of the special enrollment period may vary among Exchanges depending on total Exchange enrollment and Exchange plan rates and pricing practices. Given these variable factors, we requested comments regarding anticipated costs, benefits and implementation approaches among Exchanges to assist in forming a future estimate.

We do not anticipate this provision to significantly increase regulatory burden on issuers, but acknowledge issuers may encounter marginal costs associated with processing new enrollments and terminations related to the special enrollment period, and direct enrollment entities may also face minor implementation costs associated with updating their applications and systems to include the new special enrollment period. We estimate that it will take a mid-level software developer²⁰⁴ (at an hourly rate of \$107.48) approximately 10 hours to make the required modifications to the direct enrollment entity's applications and system logic. We estimate a one-time cost burden of approximately \$1,075 per direct enrollment entity. We further estimate a total one-time burden for 35 direct enrollment entities will be approximately 350 hours with an

²⁰⁴ Bureau of Labor Statistics mean hourly wage for a Software Developer, Systems Software (Occupational Code 15-1133) at \$53.74 an hour, plus 100 percent fringe.

equivalent cost of approximately \$37,618.

Because this policy provides improved pathways to continuous coverage for special enrollment period-eligible consumers, we anticipate that the proposal will promote continuous coverage for consumers and thereby have a positive effect on the individual market risk pool. Additionally, we anticipate that eligible consumers may experience reduced out-of-pocket costs related to health care expenses resulting from access to more affordable health plans and a new pathway to maintaining continuous health care coverage, compared to if they had to drop out of off-Exchange coverage and pay out-of-pocket for all health care expenses incurred for the remainder of the year. We estimate that approximately 4,700 new consumers will use this special enrollment period on an annual basis to enroll in Exchange coverage, and that these consumers will be enrolled for an average of 6 months of Exchange coverage during the benefit year. Using the plan year 2019 average monthly APTC amount of \$544, we estimate total APTC transferred to consumers as a result of the proposed special enrollment period will be approximately \$15,340,800 annually.²⁰⁵

We invited comments on the potential costs and savings to Exchanges, issuers, direct enrollment entities, and consumers associated with the proposed special enrollment period. We did not receive comments on the cost estimates contained in these proposal.

8. Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the amendment to § 155.605(e) will create additional costs or burdens on Exchanges, and we anticipate it will decrease burden on consumers. The addition of § 155.605(e)(5) will enable individuals to claim a general hardship exemption on their federal income tax return for 2018 without an exemption certificate number from an Exchange. This policy will allow for more flexibility and will not result in any additional costs or burdens for issuers. The reduction in burden to consumers is discussed in the Collection of Information Requirements section.

9. FFE and SBE-FP 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

²⁰⁵ ASPE "2019 Health Plan Choice and Premiums in HealthCare.gov states." <https://aspe.hhs.gov/system/files/pdf/260041/2019LandscapeBrief.pdf>.

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 or SBE-FP. In this final rule, for the 2020 benefit year, we finalize an FFE user fee rate of 3.0 percent of the monthly premium, and SBE-FP user fee rate of 2.5 percent of the monthly premium. We estimate similar FFE and SBE-FP user fee transfers as those estimated for prior benefit years, and therefore, we finalized no changes to transfers from issuers to the federal government due to the finalized lower FFE and SBE-FP user fee rates.

10. Prohibition on Discrimination (§ 156.125)

In the preamble to § 156.125, we discuss a potentially discriminatory benefit design under § 156.125: the exclusion of MAT drugs for the

treatment of opioid use disorder while covering the same drugs for other medically necessary purposes, such as analgesia or alcohol use disorder. Because we did not propose a change to this policy, we do not anticipate any additional burden on states or issuers. However, to the extent this clarification causes issuers to cease prohibited discriminatory practices, the clarification could help consumers obtain needed MAT, lead to better health outcomes, and reduce the burden and out-of-pocket costs individuals may have otherwise incurred in attempts to obtain MAT.

11. Provisions Related to Cost-Sharing (§ 156.130)

We are finalizing a premium adjustment percentage of 1.2895211380 for the 2020 benefit year. The annual premium adjustment percentage is used to set the rate of increase for several parameters detailed in the PPACA, including: 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 (defined at § 155.605(d)(2)), and the employer shared responsibility payments under sections 4980H(a) and 4980H(b) of the Code.

Additionally, we finalized other cost-sharing parameters using an index based on the final premium adjustment percentage for the 2020 benefit year. In § 155.605(d)(2), we are finalizing a required contribution of 8.24 percent for the 2020 benefit year, which reflects the premium adjustment percentage calculation for the 2020 benefit year detailed in preamble.²⁰⁶ In § 156.130(a)(2), we are finalizing a maximum annual limitation on cost sharing of \$8,150 for self-only coverage, and \$16,300 for other than self-only coverage. The CMS Office of the Actuary estimates that the proposed change in methodology for the calculation of the premium adjustment percentage may have the following impacts between 2019 and 2023:²⁰⁷

TABLE 14—IMPACTS OF MODIFICATIONS TO THE 2020 BENEFIT YEAR PREMIUM ADJUSTMENT PERCENTAGE

Calendar year	2019	2020	2021	2022	2023
Exchange Enrollment Impact (enrollees, thousands)	N/A	-70	-70	-70	-70
Premium Impacts:					
Gross Premium Impact (change from 2018, %)	N/A	0%	0%	0%	0%
Net Premium Impact (change from 2018, %)	N/A	1%	1%	1%	1%
Federal Impacts (dollars, millions):					
Premium Tax Credits (million, \$)	N/A	-980	-1,040	-1,090	-1,150
Health Insurance Providers Fee Impact (million, \$)	N/A	50	70	70	70
Employer Shared Responsibility Payment Impact (million, \$)	N/A	100	110	110	110
Total Federal Impact (million, \$) *		-1,130	-1,220	-1,270	-1,330

* Note: While the premium tax credit impact figures are negative to signify reductions in Federal outlays, and the Health Insurance Providers Fee and the employer shared responsibility payment figures are positive to signify increased revenue to the Federal government, they are totaled together to indicate savings for the Federal government.

As noted in Table 14, we expect that the proposed change in measure of premium growth used to calculate the premium adjustment percentage for the 2020 benefit year may result in:

- Net premium increases of approximately \$181 million per year, which is approximately one percent of 2018 benefit year net premiums, for the 2020 through 2023 benefit years. Net premiums are calculated for Exchange enrollees as premium charged by issuers minus APTC. Gross premiums will be virtually unchanged.

- A decrease in federal PTC spending of \$980 million to \$1.15 billion between 2020 and 2023, due to an increase in the PTC applicable percentage and a decline in Exchange enrollment of approximately 70,000 individuals in each benefit year, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the same premium measure proposed for the calculation of the premium adjustment percentage in this final rule for purposes of calculating the indexing of the PTC applicable percentage and

the required contribution percentage under section 36B of the Code.

- Increased Health Insurance Providers Fees on health insurance issuers of approximately \$50 million in 2020, and \$70 million in years 2021 to 2023, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the same premium measure proposed for the calculation of the premium adjustment percentage in this final rule for purposes of calculating the indexing of the Health Insurance Providers Fee.

²⁰⁶ As explained in § 155.605(d)(2), for plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 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. To calculate the final required contribution, we used the final premium adjustment percentage in the calculation: $8.00\% \times 1.0296274251 (1.2895211380 / 1.2524152976)$, or 8.24 percent.

²⁰⁷ CMS Office of the Actuary's estimates are based on their health reform model, which is an

amalgam of various estimation approaches involving federal programs, employer-sponsored insurance, and individual insurance choice models that ensure consistent estimates of coverage and spending in considering legislative changes to current law.

• Increased Employer Shared Responsibility Payments of \$100 million in 2020, and \$110 million each year between 2021 and 2023.

Comment: One commenter, citing the Center on Budget and Policy Priorities, suggests the proposal would reduce premium tax credits for millions of consumers. For example, a family of four with an annual income of \$90,000 would pay \$220 more for their coverage (the effect would be smaller for premium tax credit recipients with lower household incomes). The commenter noted that these changes would also mean more people would be considered to have an “affordable” offer of employer coverage, and therefore, would be ineligible for the premium tax credit. These changes would reduce the overall affordability of coverage and the number of people covered.

Response: As stated elsewhere in this rule, while we acknowledge the impact of the decrease in premium tax credits, we believe this is a technical adjustment to reflect premium growth in the entire individual market. Moreover, the benefits due to the decrease in federal expenditures outweigh those concerns and will be ultimately beneficial to taxpayers. Furthermore, we note that the 2020 required contribution percentage is lower than the 2019 required contribution percentage under the finalized method for measuring premium growth.

Some of the 70,000 individuals estimated to not enroll in Exchange coverage each year as a result of the proposed change in the measure of premium growth used to calculate the premium adjustment percentage may purchase short-term, limited-duration insurance or join a spouse’s plan, though a majority is likely to become uninsured. Either transition may result in greater exposure to health care costs, which previous research suggests reduces utilization of health care services.²⁰⁸ Economic distortions may be reduced, and economic efficiency and social benefits improved, because these individuals will be bearing a larger share of the costs of their own health care consumption, potentially reducing spending on health care services that are personally only

²⁰⁸ Manning, W.G., Newhouse, J.P., Duan, N., Keeler, E.B., & Leibowitz, A. (1987). Health insurance and the demand for medical care: evidence from a randomized experiment. *The American economic review*, 251–277; Keeler, E.B., & Rolph, J.E. (1988). The demand for episodes of treatment in the health insurance experiment. *Journal of health economics*, 7(4), 337–367; Finkelstein, A., et al. (2012). The Oregon health insurance experiment: evidence from the first year. *The Quarterly journal of economics*, 127(3), 1057–1106.

marginally valued but that imposes costs on the federal government through subsidies. In addition, to the extent that this final rule reduces federal outlays and thereby reduces the need to collect taxes in the future, the distortionary effects of taxation on the economy may be reduced. However, the increased number of uninsured may increase federal and state uncompensated care costs.

As noted in this rule, the premium adjustment percentage is the measure of premium growth that is used to set the rate of increase for the maximum annual limitation on cost sharing, defined at § 156.130(a). In § 156.130(a)(2), we proposed a maximum annual limitation on cost sharing of \$8,200 for self-only coverage. We are finalizing a maximum annual limitation on cost sharing of \$8,150. Additionally, we proposed and are finalizing reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analyses in previous Payment Notices, we developed three test silver level QHPs and analyzed the impact on their AVs of the reductions described in the PPACA to the estimated 2020 maximum annual limitation on cost sharing for self-only coverage. We do not believe the finalized changes to the reductions in the maximum annual limitation on cost sharing for silver plan variations will result in a significant economic impact.

12. 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 final 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 assumption may understate or overstate the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters will be a fair estimate of the number of reviewers of this final rule.

We are required to issue a substantial portion of this final 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 final 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 issue 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 final rule is \$107.38 per hour, including overhead and fringe benefits.²⁰⁹ We received 26,129 comments on the proposed rule, of which 497 comments were unique and 25,632 comments were substantially similar to one of eight different letters. We assume that for form letters, only the staff at the organization that arranged for those letters will review the final rule. Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review the relevant portions of this final rule that causes unanticipated burden. We assume that 497 entities will review this final rule. For each entity that reviews the rule, the estimated a cost of approximately \$107.38. Therefore, we estimate that the total cost of reviewing this regulation is approximately \$53,368 (\$107.38 × 497 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives to the presented proposals. In this rule, we discuss the key regulatory alternatives to the finalized provisions that we considered.

In proposing the risk adjustment model recalibration in part 153, we considered multiple alternatives such as maintaining the prior year’s recalibration methodology of recalibrating the models using 2 years of MarketScan® data and the most recent year of EDGE data. We also considered recalibrating the models using the most recent year of MarketScan® data available (2017) and the 2 most recent years of enrollee-level EDGE data (2016 and 2017). However, we are finalizing recalibration of the models using 3 years of blended data from the following sources: the 2 most recent years of enrollee-level EDGE data (2016 and 2017) available and 2015 MarketScan® data.

Regarding proposed changes to §§ 155.210 and 155.215, we considered taking no action to amend certain Navigator training requirements and duties, but determined that the proposed changes regarding training requirements will provide Exchanges

²⁰⁹ https://www.bls.gov/oes/current/oes_nat.htm.

with needed flexibility, and the proposed changes regarding duties of FFE Navigators will help reduce burden on FFE Navigators.

In proposing revisions to § 155.221, we considered maintaining the existing regulatory framework that established standards for issuers and web-brokers participating in direct enrollment in separate sections, but we believe streamlining and consolidating the requirements applicable to all direct enrollment entities, when possible, improves clarity and promotes fair competition. For the display requirements at § 155.221(b), we contemplated maintaining the current standards in regulations and guidance, but based on feedback received from direct enrollment entities, we believe the current framework may have caused confusion and limited innovation. Therefore, we determined that the establishment of clarified standards for the marketing and display of QHPs and non-QHPs is the best way to provide greater clarity for direct enrollment entities about what is required to minimize the potential for consumer confusion, while allowing direct enrollment entities more flexibility to be innovative in the marketing of non-QHPs to consumers who are interested in those products. For the addition of a new § 155.221(c), we considered continuing to limit the authority to use application assisters to QHP issuers. However, to promote fair competition for all direct enrollment entities and issuers, we believe a better approach is to expand this authority to include all direct enrollment entities and all issuers.

In proposing revisions to § 155.420 governing Exchange special enrollment periods, we considered broader eligibility requirements for the special enrollment period proposed at § 155.420(d)(6)(v). We considered if a special enrollment period could be offered without a decrease in household income to all Exchange applicants who were enrolled in MEC and determined eligible for APTC by the Exchange, or if changes in the applicant's household size could be considered in the eligibility criteria for this special enrollment period. We determined that eliminating the criteria for a decrease in household income will be problematic because it eliminates a triggering event for the special enrollment period and could allow for consumers who are potentially APTC-eligible to avoid the metal level restrictions in paragraph (a)(4) of this section by initially enrolling in off-Exchange coverage and then later choosing to buy a higher or lower level of coverage mid-year. We

also determined that verification of household size changes will be operationally problematic, as electronic data sources will not reflect recent changes to household size. Further, the special enrollment periods at § 155.420(d)(2)(i) are currently available to qualified individuals whose household size changes due to gaining or becoming a dependent and already provides a pathway to Exchange coverage for individuals in this situation.

We also considered if the special enrollment period proposed at § 155.420(d)(6)(v) could be offered without a prior coverage requirement and determined that this requirement is necessary to ensure the special enrollment period is only available to the intended population, to promote continuous coverage among individual market enrollees, and to protect the individual market risk pools against adverse selection. Finally we considered the impact of not proposing this special enrollment period. Without the proposed special enrollment period at § 155.420(d)(6)(v), unsubsidized off-Exchange consumers who experience a decrease in household income midyear and are determined APTC eligible will remain without a pathway to Exchange coverage. These consumers will remain at risk of terminating their unsubsidized coverage midyear because it is unaffordable, rather than maintaining continuous enrollment in health coverage by transitioning to an Exchange plan.

Regarding the proposed change to § 155.605(e) to allow consumers to claim all general hardship exemptions through the federal tax filing process for the 2018 tax year, we considered that without the recommended revisions to § 155.605(e), individuals may experience a general hardship that prevents them from obtaining qualifying health coverage, and may experience undue burden to apply and qualify for an exemption from the individual shared responsibility provision. This change allows for more flexibility for individuals to claim these exemptions through the IRS tax filing process for the 2018 tax year.

We are finalizing our proposed change to the premium measure used in the premium adjustment percentage calculation under § 156.130 to use a private health insurance premium measure (excluding Medigap and property and casualty insurance) in addition to employer sponsored health insurance premiums. However, we considered other alternatives to the final premium measure and methodology for calculating the premium adjustment

percentage for the 2020 benefit year. We considered finalizing our proposed method with a gradual phase-in. We also considered maintaining our previous process of using employer-sponsored insurance premium amounts. In addition, we considered using NHEA estimates and projections of private health insurance premium measure, which includes premiums for employer-sponsored insurance, direct purchase insurance (which includes Medigap insurance), and property and casualty insurance. However, we ultimately decided not to propose or finalize the use of a private health insurance measure that included Medigap insurance because we believed it was inappropriate to include Medigap premiums in the measure as this type of coverage is not considered primary coverage for those enrollees who supplement their Medicare coverage with these plans. Moreover, although total spending for private health insurance in the NHEAs includes the medical portion of accident insurance (property and casualty insurance), we did not believe it would be appropriate to include those expenditures for this purpose as they are associated with policies that do not serve as a primary source of health insurance coverage. For the reasons explained in more detail in the preamble for § 156.130, we ultimately decided to finalize the proposal as proposed.

At § 156.130 we also proposed that plans not be required to count drug manufacturer coupons toward the annual limitation on cost sharing, starting with plan years beginning on or after January 1, 2020. We considered not proposing this flexibility, as these coupons may result in lower costs to individual consumers. However, manufacturer coupons may incentivize selection of higher-cost drugs when a less costly therapeutic equivalent is available which can distort the market and the true costs of drugs, adding significant long-term costs to the health care system.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small

government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, the standards for the risk adjustment and risk adjustment data validation programs are intended to stabilize premiums. 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.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$38.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$32.5 million or less.²¹⁰ We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report²¹¹ submissions for the 2016 MLR reporting year, approximately 85 out of over 520 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 79 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 will result in their revenues exceeding \$38.5 million.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of

the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not affect small rural hospitals. Therefore, the Secretary has determined that this will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a rule that includes any federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 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 issues a 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, we have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis.

While developing this final rule, we attempted to balance the states’ interests in regulating health insurance issuers with the need to ensure market stability. By doing so, it is our 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 state. Current State Exchanges charge user fees to issuers.

In our view, while this final rule will not impose substantial direct requirement costs on state and local governments, this regulation has Federalism implications because it finalizes a change to the Alabama risk adjustment program in the small group market based upon a proposal provided by the state. We also proposed to make the special enrollment period at § 155.420(d)(6)(v) at the option of Exchanges, to give states flexibility in whether they choose to implement it.

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 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 issues, 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.²¹²

J. Conclusion

The analysis in this rule, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation

²¹⁰ <https://www.sba.gov/document/support-table-size-standards>.

²¹¹ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

²¹² We estimate cost savings of approximately \$14.3 million in 2019 and annual cost saving of approximately \$14 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 \$8.51 million.

was reviewed by the Office of Management and Budget.

List of Subjects

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Insurance companies, Penalties, 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 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, Brokers, 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.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services amends 45 CFR as set forth below.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300–gg–92.

■ 2. Section 146.152 is amended by revising paragraph (a) to read as follows:

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (f) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

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

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

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92 as amended.

■ 4. Section 147.106 is amended by revising paragraph (a) to read as follows:

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (e) of this section, a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 5. The authority citation for part 148 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–11 300gg–91, and 300–gg92, as amended.

■ 6. Section 148.122 is amended by revising paragraph (b)(1) to read as follows:

§ 148.122 Guaranteed renewability of individual health insurance coverage.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (c) through (g) of this section, an issuer

must renew or continue in force the coverage at the option of the individual.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 7. The authority citation for part 153 is revised to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 8. Section 153.20 is amended by revising the definition of “Risk adjustment covered plan” to read as follows:

§ 153.20 Definitions.

* * * * *

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 § 146.145(b) of this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.

* * * * *

■ 9. Section 153.320 is amended by revising 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 catastrophic, individual non-catastrophic, small group, or merged markets risk pools 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 risk pool;

(ii) The adjustment percentage of up to 50 percent requested for the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool; 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 catastrophic, individual non-catastrophic, small group, or merged market risk pool, 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 transfers in the individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by August 1 of the benefit year that is 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 rule and make the supporting evidence available to the public for comment, except to the extent the State requests HHS not publish certain supporting evidence because it contains trade secrets or confidential commercial or financial information as defined in HHS' Freedom of Information regulations under 45 CFR 5.31(d). HHS will publish any approved 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 reduction 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 risk pool, 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's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool 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 catastrophic, individual non-catastrophic, small group, or merged market risk pool 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 applicable State market risk pool.

■ 10. Section 153.630 is amended by—

■ a. Revising paragraphs (b)(10) and (d)(2); and

■ b. Adding paragraph (g)

The revisions and addition read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(10) If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default data validation charge.

* * * * *

(d) * * *

(2) Within 30 calendar days of the notification by HHS of the findings of a second validation audit (if applicable) or the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.

* * * * *

(g) *Exemptions.* An issuer of a risk adjustment covered plan will be exempted by HHS from the data validation requirement set forth in paragraph (b) of this section for a given benefit year if:

(1) The issuer has 500 or fewer billable member months of enrollment in the individual, small group and merged markets (as applicable) for the applicable benefit year, calculated on a Statewide basis;

(2) The issuer is at or below the materiality threshold as defined by HHS and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audits); or

(3) The issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that:

(i) The issuer provides to HHS, in the manner and timeframe specified by HHS, an attestation that the issuer is in liquidation or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer; and

(ii) The issuer is not a positive error rate outlier under the error estimation methodology in risk adjustment data validation for the prior benefit year of risk adjustment data validation.

(iii) For purposes of this paragraph (g)(3), liquidation means that a State court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 11. The authority citation for part 155 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 12. Section 155.20 is amended by adding definitions of “Direct enrollment entity,” “Direct enrollment entity application assister,” “Direct enrollment technology provider,” and “Web-broker” to read as follows:

§ 155.20 Definitions.

* * * * *

Direct enrollment entity means an entity that an Exchange permits to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by § 155.220(c)(3), § 155.221, or § 156.1230 of this subchapter.

Direct enrollment entity application assister means an employee, contractor, or agent of a direct enrollment entity who is not licensed as an agent, broker, or producer under State law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs.

Direct enrollment technology provider means a type of web-broker business entity that is not a licensed agent, broker, or producer under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate

participation in direct enrollment under §§ 155.220(c)(3) and 155.221.

* * * * *

Web-broker means an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in qualified health plans offered through the Exchange as described in §§ 155.220(c)(3) and 155.221. The term also includes a direct enrollment technology provider.

■ 13. Section 155.205 is amended by revising paragraph (a) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* The Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (2)(i), and (3) of this section, unless it is an Exchange described in paragraphs (a)(1) or (2) of this section, in which case, the Exchange must provide at a minimum a toll-free telephone hotline that includes the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers to the applicable Exchange website and other applicable resources.

(1) An Exchange described in this paragraph is one that enters into a Federal platform agreement through which it relies on HHS to operate its eligibility and enrollment functions, as applicable.

(2) An Exchange described in this paragraph is a SHOP that does not provide for enrollment in SHOP coverage through an online SHOP enrollment platform, but rather provides for enrollment through SHOP issuers or agents and brokers registered with the Exchange.

* * * * *

■ 14. Section 155.210 is amended by—

- a. Revising paragraphs (b)(2) introductory text, (b)(2)(iii), and (iv);
- b. Removing paragraphs (b)(2)(v) through (ix); and
- c. Revising paragraph (e)(9) introductory text.

The revisions read as follows:

§ 155.210 Navigator program standards.

* * * * *

(b) * * *

(2) A set of training standards, to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure

the entities and individuals are qualified to engage in Navigator activities, including training standards on the following topics:

* * * * *

(iii) The range of QHP options and insurance affordability programs; and

(iv) The privacy and security standards applicable under § 155.260.

* * * * *

(e) * * *

(9) The Exchange may require or authorize Navigators to provide information and assistance with any of the following topics. In Federally-facilitated Exchanges, Navigators are required to provide information and assistance with all of the following topics under Navigator grants awarded in 2018, and will be authorized to provide information and assistance with all of the following topics under Navigator grants awarded in 2019 or any later year.

* * * * *

■ 15. Section 155.215 is amended by revising paragraph (b)(2) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(b) * * *

(2) *Training module content standards.* All individuals who carry out the consumer assistance functions under §§ 155.205(d) and (e) and 155.210 must receive training consistent with standards established by the Exchange consistent with § 155.210(b)(2).

* * * * *

■ 16. Section 155.220 is amended by—

- a. Revising the section heading;
- b. Revising paragraphs (a) introductory text, (c) introductory text, (c)(1), (c)(3)(i) introductory text and (c)(3)(i)(A), (c)(3)(i)(K) and (L), (c)(3)(ii) introductory text, (c)(4) introductory text, (c)(4)(i) introductory text, (c)(4)(i)(A), (c)(4)(i)(E), (c)(4)(i)(F), (c)(4)(ii), (c)(5), (d) introductory text, (d)(2), (e), (f)(1), (f)(2), (f)(3) introductory text, (f)(3)(i), (f)(4), (g)(1), (g)(2) introductory text, (g)(2)(iii), (g)(2)(iv), (g)(3), (g)(4), (g)(5)(i), (g)(5)(ii), (g)(5)(iii), (h)(1), (h)(2), (h)(3), (i), (j)(1) introductory text, (j)(3), (k)(1) introductory text, (k)(2);
- c. Adding paragraph (k)(3);
- d. Revising paragraph (l); and
- e. Adding paragraph (m).

The additions and revisions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

(a) *General rule.* A State may permit agents, brokers, and web-brokers to—

* * * * *

(c) *Enrollment through the Exchange.* A qualified individual may be enrolled in a QHP through the Exchange with the assistance of an agent, broker, or web-broker if—

(1) The agent, broker, or web-broker ensures the applicant's completion of an eligibility verification and enrollment application through the Exchange internet website as described in § 155.405, or ensures that the eligibility application information is submitted for an eligibility determination through the Exchange-approved web service subject to meeting the requirements in paragraphs (c)(3)(ii) and (c)(4)(i)(F) of this section;

* * * * *

(3)(i) When an internet website of a web-broker is used to complete the QHP selection, at a minimum the internet website must:

(A) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), and to the extent that not all information required under § 155.205(b)(1) is displayed on the web-broker's internet website for a QHP, prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a Web link to the Exchange website;

* * * * *

(K) Comply with the applicable requirements in § 155.221; and

(L) Not display QHP recommendations based on compensation the agent, broker, or web-broker receives from QHP issuers.

(ii) When an internet website of a web-broker is used to complete the Exchange eligibility application, at a minimum the internet website must:

* * * * *

(4) When an agent or broker, through a contract or other arrangement, uses the internet website of a web-broker to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application in the Federally-facilitated Exchange:

(i) The web-broker who makes the website available must:

(A) Provide HHS with a list of agents and brokers who enter into such a contract or other arrangement to use the

web-broker's website, in a form and manner to be specified by HHS;

* * * * *

(E) Report to HHS and applicable State departments of insurance any potential material breach of the standards in paragraphs (c) and (d) of this section, or the agreement entered into under § 155.260(b), by the agent or broker accessing the internet website, should it become aware of any such potential breach. A web-broker that provides access to its website to complete the QHP selection or the Exchange eligibility application or ability to transact information with HHS to another web-broker website is responsible for ensuring compliance with applicable requirements in paragraph (c)(3) of this section for any web pages of the other web-broker's website that assist consumers, applicants, qualified individuals, and enrollees in applying for APTC and CSRs for QHPs, or in completing enrollment in QHPs, offered in the Exchanges.

(F) When an internet website of a web-broker is used to complete the Exchange eligibility application, obtain HHS approval verifying that all requirements in this section are met.

(ii) HHS retains the right to temporarily suspend the ability of a web-broker making its website available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction.

(5) HHS or its designee may periodically monitor and audit an agent, broker, or web-broker under this subpart to assess its compliance with the applicable requirements of this section.

(d) *Agreement.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with the terms of an agreement between the agent, broker, or web-broker and the Exchange under which the agent, broker, or web-broker at least:

* * * * *

(2) Receives training in the range of QHP options and insurance affordability programs, except that a licensed agent or broker entity that registers with the Federally-facilitated Exchange in its capacity as a business organized under the laws of a State, and not as an individual person, and direct

enrollment technology providers are exempt from this requirement; and

* * * * *

(e) *Compliance with State law.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with applicable State law related to agents, brokers, or web-brokers including applicable State law related to confidentiality and conflicts of interest.

(f) * * *

(1) An agent, broker, or web-broker may terminate its agreement with HHS by sending to HHS a written notice at least 30 days in advance of the date of intended termination.

(2) The notice must include the intended date of termination, but if it does not specify a date of termination, or the date provided is not acceptable to HHS, HHS may set a different termination date that will be no less than 30 days from the date on the agent's, broker's, or web-broker's notice of termination.

(3) Prior to the date of termination, an agent, broker, or web-broker should—

(i) Notify applicants, qualified individuals, or enrollees that the agent, broker, or web-broker is assisting, of the agent's, broker's, or web-broker's intended date of termination;

* * * * *

(4) When the agreement between the agent, broker, or web-broker and the Exchange under paragraph (d) of this section is terminated under paragraph (f) of this section, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under § 155.260(b) will also be terminated through the termination without cause process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(g) * * *

(1) If, in HHS' determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe, HHS may terminate an agent's, broker's, or web-broker's agreement with the Federally-facilitated Exchange for cause.

(2) An agent, broker, or web-broker may be determined noncompliant if HHS finds that the agent, broker, or web-broker violated—

* * * * *

(iii) Any State law applicable to agents, brokers, or web-brokers, as required under paragraph (e) of this section, including but not limited to State laws related to confidentiality and conflicts of interest; or

(iv) Any Federal law applicable to agents, brokers, or web-brokers.

* * * * *

(3)(i) Except as provided in paragraph (g)(3)(ii) of this section, HHS will notify the agent, broker, or web-broker of the specific finding of noncompliance or pattern of noncompliance made under paragraph (g)(1) of this section, and after 30 days from the date of the notice, may terminate the agreement for cause if the matter is not resolved to the satisfaction of HHS.

(ii) HHS may immediately terminate the agreement for cause upon notice to the agent or broker without any further opportunity to resolve the matter if an agent or broker fails to maintain the appropriate license under State law as an agent, broker, or insurance producer in every State in which the agent or broker actively assists consumers with applying for advance payments of the premium tax credit or cost-sharing reductions or with enrolling in QHPs through the Federally-facilitated Exchanges.

(4) After the applicable period in paragraph (g)(3) of this section has elapsed and the agreement under paragraph (d) of this section is terminated, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under § 155.260(b)(2) will also be terminated through the process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally

identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(5) * * *

(i)(A) If HHS reasonably suspects that an agent, broker, or web-broker may have engaged in fraud, or in abusive conduct that may cause imminent or ongoing consumer harm using personally identifiable information of an Exchange enrollee or applicant or in connection with an Exchange enrollment or application, HHS may temporarily suspend the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for up to 90 calendar days. Suspension will be effective on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the suspension of the agreements.

(B) The agent, broker, or web-broker may submit evidence in a form and manner to be specified by HHS, to rebut the allegation during this 90-day period. If the agent, broker, or web-broker submits such evidence during the suspension period, HHS will review the evidence and make a determination whether to lift the suspension within 30 days of receipt of such evidence. If the rebuttal evidence does not persuade HHS to lift the suspension, or if the agent, broker, or web-broker fails to submit rebuttal evidence during the suspension period, HHS may terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause under paragraph (g)(5)(ii) of this section.

(ii) If there is a finding or determination by a Federal or State entity that an agent, broker, or web-broker engaged in fraud, or abusive conduct that may result in imminent or ongoing consumer harm, using personally identifiable information of Exchange enrollees or applicants or in connection with an Exchange enrollment or application, HHS will terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause. The termination will be effective starting on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the termination of the agreements.

(iii) During the suspension period under paragraph (g)(5)(i) of this section and following termination of the agreements under paragraph (g)(5)(i)(B) or (g)(5)(ii) of this section, the agent, broker, or web-broker will not be registered with the Federally-facilitated Exchanges, or be permitted to assist

with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

* * * * *

(h) * * *

(1) *Request for reconsideration.* An agent, broker, or web-broker whose agreement with the Federally-facilitated Exchange has been terminated may request reconsideration of such action in the manner and form established by HHS.

(2) *Timeframe for request.* The agent, broker, or web-broker must submit a request for reconsideration to the HHS reconsideration entity within 30 calendar days of the date of the written notice from HHS.

(3) *Notice of reconsideration decision.* The HHS reconsideration entity will provide the agent, broker, or web-broker with a written notice of the reconsideration decision within 30 calendar days of the date it receives the request for reconsideration. This decision will constitute HHS' final determination.

* * * * *

(i) *Use of agents' and brokers' and web-brokers' internet websites for SHOP.* For plan years beginning on or after January 1, 2015, in States that permit this activity under State law, a SHOP may permit agents, brokers, and web-brokers to use an internet website to assist qualified employers and facilitate enrollment of enrollees in a QHP through the Exchange, under paragraph (c)(3) of this section.

(j) * * *

(1) An agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through a Federally-facilitated Exchange, must—

* * * * *

(3) If an agent, broker, or web-broker fails to provide correct information, he, she, or it will nonetheless be deemed in

compliance with paragraphs (j)(2)(i) and (ii) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information and that the agent, broker, or web-broker acted in good faith.

(k) * * *

(1) If HHS determines that an agent, broker, or web-broker has failed to comply with the requirements of this section, in addition to any other available remedies, that agent, broker, or web-broker—

* * * * *

(2) HHS will notify the agent, broker, or web-broker of the proposed imposition of penalties under paragraph (k)(1)(i) of this section as part of the termination notice issued under paragraph (g) of this section and, after 30 calendar days from the date of the notice, may impose the penalty if the agent, broker, or web-broker has not requested a reconsideration under paragraph (h) of this section. The proposed imposition of penalties under paragraph (k)(1)(ii) of this section will follow the process outlined under § 155.285.

(3) HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

(l) *Application to State Exchanges using a Federal platform.* An agent, broker, or web-broker who enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a State Exchange using the Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using the Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

(m) *Web-broker agreement suspension, termination, and denial and information collection.* (1) A web-broker's agreement executed under paragraph (d) of this section, may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges under paragraph (k)(1)(i) of this section, based on the actions of its officers, employees, contractors, or agents, whether or not the officer, employee, contractor, or

agent is registered with the Exchange as an agent or broker.

(2) A web-broker's agreement executed under paragraph (d) of this section may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges under paragraph (k)(1)(i) of this section, if it is under the common ownership or control or is an affiliated business of another web-broker that had its agreement suspended or terminated under paragraph (g) of this section.

(3) The Exchange may collect information from a web-broker during its registration with the Exchange under paragraph (d)(1) of this section, or at another time on an annual basis, in a form and manner to be specified by HHS, sufficient to establish the identities of the individuals who comprise its corporate ownership and leadership and to ascertain any corporate or business relationships it has with other entities that may seek to register with the Federally-facilitated Exchange as web-brokers.

■ 17. Section 155.221 is amended by—

- a. Revising the section heading;
- b. Redesignating paragraphs (a), (b), and (c) as paragraphs (e), (f), and (g), respectively;
- c. Adding paragraphs (a), (b), (c), and (d);
- d. Revising newly redesignated paragraph (e), paragraph (f) introductory text, paragraphs (f)(2), (3), (4), (6) and (7), and paragraph (g); and
- e. Adding paragraph (h).

The revisions and additions read as follows:

§ 155.221 Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.

(a) *Direct enrollment entities.* The Federally-facilitated Exchanges will permit the following entities to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to the extent permitted by applicable State law:

(1) QHP issuers that meet the applicable requirements in this section and § 156.1230 of this subchapter; and

(2) Web-brokers that meet the applicable requirements in this section and § 155.220.

(b) *Direct enrollment entity requirements.* For the Federally-facilitated Exchanges, a direct enrollment entity must:

(1) Display and market QHPs and non-QHPs on separate website pages on its non-Exchange website;

(2) Prominently display a standardized disclaimer in the form and manner provided by HHS;

(3) Limit marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not;

(4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection; and

(5) Comply with applicable Federal and State requirements.

(c) *Direct enrollment entity application assister requirements.* For the Federally-facilitated Exchanges, to the extent permitted under state law, a direct enrollment entity may permit its direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such direct enrollment entity ensures that each of its direct enrollment entity application assisters meets the requirements in § 155.415(b).

(d) *Federally-facilitated Exchange direct enrollment entity suspension.* HHS may immediately suspend the direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

(e) *Third parties to perform audits of direct enrollment entities.* A direct enrollment entity must engage an independent, third-party entity to conduct an initial and annual review to demonstrate the direct enrollment entity's operational readiness and compliance with applicable direct enrollment entity requirements in accordance with paragraph (b)(4) of this section prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection. The third-party entity will be a downstream or delegated entity of the direct enrollment entity that participates or wishes to participate in direct enrollment.

(f) *Third-party auditor standards.* A direct enrollment entity must satisfy the requirement to demonstrate operational readiness under paragraph (e) of this section by engaging a third-party entity that executes a written agreement with the direct enrollment entity under which the third-party entity agrees to comply with each of the following standards:

* * * * *

(2) Adheres to HHS specifications for content, format, privacy, and security in the conduct of an operational readiness review, which includes ensuring that direct enrollment entities 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 direct enrollment entities 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 direct enrollment entities 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 a direct enrollment entity for which it is conducting an operational readiness review;

* * * * *

(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 (e) 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 a direct enrollment entity's obligations in accordance with standards under paragraph (e) of this section until 10 years from the date of creation of a specific audit; and

* * * * *

(g) *Multiple auditors.* A direct enrollment entity may engage multiple third-party entities to conduct the audit under paragraph (e) of this section.

(h) *Application to State Exchanges using a Federal platform.* A direct enrollment entity that enrolls qualified individuals in coverage in a manner that constitutes enrollment through a State Exchange using the Federal platform, or assists individual market consumers with submission of applications for

advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using a Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

■ 18. Section 155.415 is revised to read as follows:

§ 155.415 Allowing issuer or direct enrollment entity application assisters to assist with eligibility applications.

(a) *Exchange option.* An Exchange, to the extent permitted by State law, may permit issuer application assisters and direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and insurance affordability programs, provided that such issuer application assisters or direct enrollment entity application assisters meet the requirements set forth in paragraph (b) of this section.

(b) *Application assister requirements.* If permitted by an Exchange under paragraph (a) of this section, and to the extent permitted by State law, an issuer may permit its issuer application assisters and a direct enrollment entity may permit its direct enrollment entity application assisters to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such issuer or direct enrollment entity ensures that each of its issuer application assisters or direct enrollment entity application assisters at least—

(1) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations, and for application assisters providing assistance in the Federally-facilitated Exchanges or a State Exchange using the Federal platform, the assisters must fulfill this requirement by completing registration and training in a form and manner to be specified by HHS;

(2) Complies with the Exchange’s privacy and security standards adopted consistent with § 155.260; and

(3) Complies with applicable State law related to the sale, solicitation, and negotiation of health insurance products, including any State licensure laws applicable to the functions to be performed by the issuer application assister or direct enrollment entity application assister, as well as State law related to confidentiality and conflicts of interest.

■ 19. Section 155.420 is amended—

■ a. By revising paragraphs (a)(5) and (b)(2)(iv);

■ b. In paragraph (d)(6)(ii) by removing “; or” and adding in its place “;”;

■ c. In paragraph (d)(6)(iii) by removing “.” and adding in its place “;”;

■ d. In paragraph (d)(6)(iv) by removing “;” and adding in its place “; or”; and

■ e. By adding paragraph (d)(6)(v).

The addition reads as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(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) or demonstrate that they had coverage as described in paragraphs (d)(1)(iii) or (iv) of this section 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) * * *

(iv) If a qualified individual, enrollee, or dependent, as applicable, loses coverage as described in paragraph (d)(1) or (d)(6)(iii) of this section, gains access to a new QHP as described in paragraph (d)(7) of this section, becomes newly eligible for enrollment in a QHP through the Exchange in accordance with § 155.305(a)(2) as described in paragraph (d)(3) of this section, or becomes newly eligible for advance payments of the premium tax credit in conjunction with a permanent move as described in paragraph (d)(6)(iv) of this section, and if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is the first day of the month following the date of the triggering event. If the plan selection is made after the date of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange.

* * * * *

(d) * * *

(6) * * *

(v) At the option of the Exchange, the qualified individual, or his or her dependent—

(A) Experiences a decrease in household income;

(B) Is newly determined eligible by the Exchange for advance payments of the premium tax credit; and

(C) Had minimum essential coverage as described in 26 CFR 1.5000A-1(b) for one or more days during the 60 days preceding the date of the financial change.

* * * * *

■ 20. Section 155.605 is amended by adding paragraph (e)(5) to read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(e) * * *

(5) *General hardship.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published September 12, 2018, entitled, “Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS)” (see <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf>) and in IRS Notice 2019-05 (see <https://www.irs.gov/pub/irs-drop/n-19-05.pdf>), for the 2018 tax year.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

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

Authority: 42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 22. Section 156.20 is amended by adding the definition of “Generic” in alphabetical order to read as follows:

§ 156.20 Definitions.

* * * * *

Generic means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved.

* * * * *

■ 23. Section 156.130 is amended by adding paragraph (h) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(h) *Use of drug manufacturer coupons.* For plan years beginning on or after January 1, 2020:

(1) Notwithstanding any other provision of this section, and to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

(2) [Reserved]

- 24. Section 156.1230 is amended by—
- a. Removing and reserving paragraph (a)(2);
- b. Revising paragraph (b)(1);
- c. Removing paragraph (b)(2); and
- d. Redesignating paragraph (b)(3) as (b)(2).

The revisions read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

- (a) * * *
- (2) [Reserved]
- (b) * * *

(1) The QHP issuer must comply with applicable requirements in § 155.221 of this subchapter.

* * * * *

Dated: March 26, 2019.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

Dated: April 2, 2019.

Alex M. Azar II,
Secretary, Department of Health and Human Services.

[FR Doc. 2019-08017 Filed 4-18-19; 4:15 pm]

BILLING CODE 4150-28-P