



DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 150, 153, 155, 156, 158, and 184

[CMS-9914-F2]

RIN 0938-AU18

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

Parameters for 2022 and Pharmacy Benefit Manager Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health & Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment program and cost-sharing parameters. It includes changes related to special enrollment periods; direct enrollment entities; the administrative appeals processes with respect to health insurance issuers and non-federal governmental group health plans; the medical loss ratio program; income verification by Exchanges; and other related topics. It also revises the regulation requiring the reporting of certain prescription drug information by qualified health plans or their pharmacy benefit managers.

DATES: These regulations are effective on [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], with the exception of the amendments to §§ 155.320(c) and 158.221(b) which are effective [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

FOR FURTHER INFORMATION CONTACT:

Jeff Wu, (301) 492-4305, Rogelyn McLean, (301) 492-4229, Grace Bristol, (410) 786-8437, Kiahana Brooks, (301) 492-5229, or Sara Rosta, (301) 492-4223 for general information.

Cam Clemmons, (206) 615-2338, for matters related to health insurance reform requirements for the group and individual insurance markets and administrative appeals for

health insurance issuers and non-federal governmental group health plans.

Allison Yadsco, (410) 786-1740, or Jacquelyn Rudich, (301) 492-5211, for matters related to risk adjustment.

Isadora Gil, (410) 786-4532, or Colleen Gravens, (301) 492-4107, for matters related to EDGE discrepancies.

Joshua Paul, (301) 492-4347, for matters related to risk adjustment data validation.

Dan Brown, (301) 492-5146, for matters related to web-brokers or direct enrollment, other than the direct enrollment option for Federally-facilitated and State Exchanges.

Nicholas Eckart, (301) 492-4452, for matters related to termination notices.

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

Marisa Beatley, (301) 492-4307, for matters related to employer-sponsored coverage verification.

Carolyn Kraemer, (301) 492-4197, for matters related to special enrollment periods for Exchange enrollment under part 155.

Katherine Bentley, (301) 492-5209, for matters related to special enrollment period verification.

Rebecca Bucchieri, (301) 492-4400, for matters related to EHB-benchmark plans and defrayal of state-required benefits.

Aaron Franz, (410) 786- 8027, for matters related to user fees.

Joshua Paul, (301) 492-4347 or Nora Simmons, (410-786-1981), for matters related to the premium adjustment percentage.

Ken Buerger, (410) 786-1190, for matters related to PBM transparency reporting requirements.

Nora Simmons, (410-786-1981), Adrienne Carter, (303) 844-5810, or Amber Bellsdale, (301) 492-4411, for matters related to disputes under 45 CFR 156.1210.

Nidhi Singh Shah, (301) 492-5110, for matters related to the Quality Rating System and

the Qualified Health Plan Enrollee Experience Survey.

Alper Ozinal, (301) 492-4178, or Jacquelyn Rudich, (301) 492-5211, for matters related to financial program audits and civil money penalties.

Adrienne Patterson, 410-786-0696, or Nora Simmons, (410-786-1981), for matters related to netting of payments under 45 CFR 156.1215 and administrative appeals under 45 CFR 156.1220.

Christina Whitefield, (301) 492-4172, for matters related to the MLR program.

SUPPLEMENTARY INFORMATION:

Future Rulemaking on Benefit and Payment Parameters for the 2022 Plan Year

In the December 4, 2020 **Federal Register**, we published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations” proposed rule (85 FR 78572) (hereinafter referred to as the “proposed rule” or “proposed 2022 Payment Notice”) that proposed to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility. In the January 19, 2021 **Federal Register** (86 FR 6138), we published a final rule that addressed a subset of the policies proposed in the proposed rule. That final rule, among other things, finalized the user fee rates for issuers offering qualified health plans through the Federally-facilitated Exchanges (FfEs) at 2.25 percent of total monthly premiums, and the user fee rate for issuers offering qualified health plans (QHPs) through State-based Exchanges on the Federal platform ((SBE-FPs) at 1.75 percent of total monthly premiums. The final rule also codified a new direct enrollment option for states served by any Exchange model to use direct enrollment technology and non-Exchange websites developed by approved web brokers, issuers and other direct enrollment partners to enroll qualified individuals in QHPs offered through the Exchange. The final rule also finalized changes to regulations governing State Innovation Waivers under section 1332 of the Affordable Care Act (ACA) that specifically incorporate

policies announced in guidance in 2018.

On January 28, 2021, President Biden issued Executive Order 14009, “Strengthening Medicaid and the Affordable Care Act,”¹ directing HHS, and the heads of all other executive departments and agencies with authorities and responsibilities related to the ACA, to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with this Administration’s policy to protect and strengthen the ACA and to make high-quality health care accessible and affordable for every American. As part of this review, HHS examined policies and requirements under the proposed 2022 Payment Notice and the January 19, 2021 final 2022 Payment Notice to analyze whether the policies under these rulemakings might undermine the Health Benefits Exchanges or the health insurance markets, and whether they may present unnecessary barriers to individuals and families attempting to access health coverage. HHS also considered whether to suspend, revise, or rescind any such actions through appropriate administrative action.

In compliance with Executive Order (E.O.) 14009 and as a result of HHS’s review of the proposed 2022 Payment Notice and the January 19, 2021 final 2022 Payment Notice, HHS intends to issue rulemaking this spring to address policies finalized in the final 2022 Payment Notice published on January 19, 2021. Specifically, in future rulemaking, HHS intends to propose new QHP issuer user fees rates for the 2022 plan year: a new FFE user fee rate of 2.75 percent of total monthly premiums; and a new SBE-FP user fee rate of 2.25 percent of monthly premiums. We also intend to revisit the Exchange Direct Enrollment (DE) option for states and the changes to regulations governing State Innovation Waivers under section 1332 of the ACA. HHS is of the view that pursuit of these proposals is consistent with E.O. 14009, and this Administration’s goal of protecting and strengthening the ACA and making high-quality health care accessible and affordable for every American.

Table of Contents

¹ 86 FR 7793 (February 2, 2021).

- I. Executive Summary
- II. Background
 - A. Legislative and Regulatory Overview
 - B. Stakeholder Consultation and Input
 - C. Structure of Proposed Rule
- III. Summary of the Proposed Provisions to the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule
 - A. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets
 - B. Part 150 – CMS Enforcement in Group and Individual Markets
 - C. Part 153 – Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment
 - D. Part 155 – Exchange Establishment Standards and Other Related Standards under the Affordable Care Act
 - E. Part 156 – Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges
 - F. Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements
 - G. Part 184 – Pharmacy Benefit Manager Standards under the Affordable Care Act
- IV. Implementation of the Decision in *City of Columbus, et al. v. Cochran*
- V. Collection of Information Requirements
 - A. Wage Estimates
 - B. ICRs Regarding Submission of Adjusted Premium Amounts for Risk Adjustment
 - C. ICRs Regarding Direct Enrollment Agents and Brokers
 - D. ICRs Regarding Prescription Drug Distribution and Cost Reporting by QHP Issuers and PBMs
 - E. ICRs Regarding Medical Loss Ratio

- F. Summary of Annual Burden Estimates for Proposed Requirements
- G. Submission of PRA Related Comments
- VI. Waiver of Proposed Rulemaking and Delay in Effective Date
- VII. 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. Executive Summary

American Health Benefit Exchanges, or “Exchanges,” are entities established under the Affordable Care Act (ACA)² through which qualified individuals and qualified employers can purchase health insurance coverage in QHPs. Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) 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 ACA also established the risk adjustment program, which is intended to increase the workability of the ACA regulatory changes in the individual and small group markets, both on- and off-Exchange.

In the December 4, 2020 **Federal Register**, we published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy

² The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), which amended and revised several provisions of the ACA, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the “Affordable Care Act” or “ACA.”

Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations” proposed rule (85 FR 78572) (hereinafter referred to as the “proposed rule” or “proposed 2022 Payment Notice”) that proposed to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility. In the proposed rule, we proposed to amend provisions and parameters to implement many ACA programs and requirements, with a focus on maintaining a stable regulatory environment. As proposed, the changes would provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs. The proposals would also provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

Risk adjustment continues to be a core program in the individual and small group markets both on and off Exchanges, and some of the major proposals from the proposed rule included recalibrated parameters for the HHS-operated risk adjustment methodology. We also proposed changes to the risk adjustment models to include a two-stage specification in the adult and child models, add severity and transplant indicators interacted with hierarchical condition category (HCC) counts factors to the adult and child models, and proposed to modify the enrollment duration factors in the adult models. Additionally, we proposed clarifications to the process for HHS to audit issuers of risk adjustment covered plans and reinsurance-eligible plans and also proposed to establish authority for HHS to conduct compliance review of these issuers.

As we do every year in the HHS notice of benefit and payment parameters, we proposed updated parameters applicable in the individual and small group markets (including merged markets). We proposed the 2022 benefit year user fee rates for issuers offering plans through the Exchanges on the Federal platform. We proposed lowering the Federally-facilitated Exchange (FFE) and State-Exchange on the Federal platform (SBE-FP) user fees rates to 2.25 and 1.75 percent of total monthly premiums, respectively, in order to reflect enrollment, premium and

HHS contract estimates for the 2022 plan year. We also proposed user fee rates of 1.5 percent of total monthly premiums for FFE and SBE-FP states that elect the Exchange DE option.³ These user fee proposals were finalized in the final rule published on January 19, 2021 (86 FR 6138).

We proposed the 2022 benefit year premium adjustment percentage, required contribution percentage, and maximum annual limitations on cost sharing, including those for cost-sharing reduction (CSR) plan variations. For the 2023 benefit year and beyond, we proposed to publish these parameters in guidance annually, and if not in guidance, in the annual notice of benefit and payment parameters or another appropriate rulemaking. Additionally, we proposed clarifications to the process under which HHS conducts audits of QHP issuers to ensure compliance with federal requirements related to advance payments of the premium tax credit (APTC), CSRs, and user fees. We also proposed to establish authority for HHS to conduct compliance reviews of QHP issuers to ensure compliance with federal APTC, CSR and user fee requirements.

We proposed changes to the information that FFE-registered web-brokers are required to display on their websites. In addition, we proposed amendments to codify more detail describing the operational readiness reviews that must be successfully completed as a prerequisite to a web-broker's non-Exchange website being approved for use by consumers to complete an Exchange eligibility application or a QHP selection. We similarly proposed to add additional detail about the operational readiness reviews applicable to direct enrollment entities.

Stable and affordable Exchanges with healthy risk pools are necessary for ensuring consumers maintain stable access to health insurance options. In order to minimize the potential for adverse selection in the Exchanges, we shared our future plans for rulemaking under which we will propose requirements related to Exchange verifications of whether applicants for QHP coverage with APTC or CSR have access to employer sponsored coverage that is affordable and

³ As noted below, the proposals to establish the Exchange DE option were finalized, with modifications, in the final rule published on January 19, 2021 (86 FR 6138).

offers minimum value. We proposed to extend our current enforcement posture under which Exchanges may exercise flexibility not to implement risk-based employer sponsored coverage verification and to remove the requirement that Exchanges select a statistically random sample of applicants when no electronic data sources are available.

We proposed new rules related to special enrollment periods. In addition, we proposed to require Exchanges to conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods granted to consumers not already enrolled in coverage through the applicable Exchange.

We also proposed minor procedural changes to provisions regarding administrative hearings in parts 150 and 156 to align with the Departmental Appeals Board's current practices for administrative hearings to appeal civil money penalties (CMPs).

We proposed to release additional data from the QHP Enrollee Experience Survey (QHP Enrollee Survey). We also solicited comments on potential changes to the framework for the Quality Rating System (QRS) to support alignment with other CMS quality reporting programs and to further balance the individual survey and clinical quality measures on the overall quality scores. We noted that we were considering ways to modify the hierarchical structure for the QRS, which is how the measures are organized together for maximum simplicity and understanding of the quality rating information provided by the QRS.

We proposed revisions to the regulations requiring the collection of certain prescription drug data from QHP issuers, and proposed to implement a requirement for the reporting of this data from pharmacy benefit managers (PBMs) when a QHP issuer contracts with a PBM to administer its prescription drug benefit.

We proposed to further regulate the standards related to QHP issuers' acceptance of payments for premiums and cost sharing. We also proposed to make clarifications to the network adequacy rules to reflect that § 156.230 does not apply to indemnity plans seeking QHP certification. These proposals were finalized in the final rule published on January 19, 2021 (86

FR 6138).

We proposed to establish a new Exchange DE option under which a State Exchange, State-based Exchange on the Federal platform or an FFE state (through an agreement with HHS) can leverage the potential of direct enrollment to offer consumers an enhanced QHP shopping experience. As proposed, instead of operating a centralized enrollment website, states could use direct enrollment technology to establish direct pathways to QHP issuers, web-brokers, and agents and brokers through which consumers would apply for and enroll in a QHP and receive a determination of eligibility for APTC and CSRs. The proposals for the Exchange DE option were finalized, with modifications, in the final rule published on January 19, 2021 (86 FR 6138).

We proposed to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for medical loss ratio (MLR) reporting and rebate calculation purposes. We additionally proposed to explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and the filing of the MLR Annual Reporting Form, and proposed to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of any remaining rebates owed after prepayment until the following MLR reporting year. We also proposed to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules previously provided. Lastly, we proposed to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a public health emergency (PHE) declared by the Secretary of HHS in the 2021 benefit year and beyond, when such credits are permitted by HHS.

In the proposed rule, the Secretaries of HHS and the Department of the Treasury proposed to reference and incorporate specific guidance published in the **Federal Register** in order to give states certainty regarding the requirements to receive and maintain approval by the Departments for State Innovation Waivers under section 1332 of the ACA. This proposal and the accompanying regulatory updates were finalized in the final rule published on January 19, 2021

(86 FR 6138).

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.

These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans⁴ and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.

Section 2702 of the PHS Act, as added by the ACA, establishes requirements for guaranteed availability of coverage in the group and individual markets, including qualifying events that trigger special enrollment periods under section 2702(b) of the PHS Act.⁵

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

Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group insurance market requirements contained in Part A of title XXVII of the PHS Act with respect to health insurance issuers when a state does not have authority to enforce or fails to substantially enforce these provisions and with respect to group health plans that are non-federal governmental plans. Section 1301(a)(1)(B) of the ACA directs all issuers of QHPs to cover the Essential Health Benefit (EHB) package described in section

⁴ The term “group health plan” is used in title XXVII of the PHS Act and is distinct from the term “health plan” as used in other provisions of title I of ACA. The term “health plan” does not include self-insured group health plans.

⁵ Before enactment of the ACA, HIPAA amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

1302(a) of the ACA, including coverage of the services described in section 1302(b) of the ACA, adherence to the cost-sharing limits described in section 1302(c) of the ACA, and meeting the actuarial value (AV) levels established in section 1302(d) of the ACA. 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 ACA.

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary), cost-sharing limits, and AV requirements. Section 1302(b) of the ACA 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.

To set cost-sharing limits, section 1302(c)(4) of the ACA 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: (1) the maximum annual limitation on cost sharing (section 1302(c)(1) of the ACA); (2) the required contribution percentage used to determine whether an individual can afford minimum essential coverage (MEC) (section 5000A of the Internal Revenue Code of 1986 (the Code), as enacted by section 1501 of the ACA); and (3) the employer shared responsibility payment amounts (section 4980H of the Code, as enacted by section 1513 of the ACA).

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

Sections 1311(b) and 1321(b) of the ACA provide that each state has the opportunity to establish an individual market Exchange that facilitates the purchase of insurance coverage by qualified individuals through QHPs and meets other standards specified in the ACA. Section 1321(c)(1) of the ACA directs the Secretary to establish and operate such Exchange within states that do not elect to establish an Exchange or, as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014.

Section 1311(c)(1) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs, including network adequacy standards at section 1311(c)(1)(B) of the ACA. Section 1311(d) of the ACA describes the minimum functions of an Exchange. Section 1311(e)(1) of the ACA 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)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state. Section 1311(c)(6)(C) of the ACA establishes special enrollment periods and section 1311(c)(6)(D) of the ACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act⁶.

Section 1311(c)(3) of the ACA directs the Secretary to develop a system to rate QHPs offered through an Exchange, based on relative quality and price. Section 1311(c)(4) of the ACA requires the Secretary to establish an enrollee satisfaction survey that evaluates the level of enrollee satisfaction of members with QHPs offered through an Exchange, for each QHP with

⁶ The Indian Health Care Improvement Act (IHCIA), the cornerstone legal authority for the provision of health care to American Indians and Alaska Natives, was made permanent when President Obama signed the bill on March 23, 2010, as part of the ACA.

more than 500 enrollees in the prior year. Further, sections 1311(c)(3) and 1311(c)(4) of the ACA require Exchanges to provide this quality rating information⁷ to individuals and employers on the Exchange's website.

Section 1312(c) of the ACA 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 ACA.

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

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

Section 1321(a) of the ACA 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 ACA. Section 1321(a)(1) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA for, among other things, the establishment and operation of Exchanges. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget

⁷ The term "quality rating information" includes the QRS scores and ratings and the results of the enrollee satisfaction survey (which is also known as the "Qualified Health Plan (QHP) Enrollee Experience Survey").

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

Section 1321(c)(2) of the ACA provides that the provisions of section 2723(b) of the PHS Act shall apply to the enforcement of the Federal Exchange standards and authorizes the Secretary to enforce the Exchange standards using CMPs on the same basis as detailed in section 2723(b) of the PHS Act.

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

Section 1332 of the ACA provides the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) with the discretion to approve a state's proposal to waive specific provisions of the ACA, provided the state's section 1332 waiver plan meets certain requirements. The Department of Health and Human Services and the Department of the Treasury (collectively, the Departments) finalized implementing regulations on February 27, 2012 (76 FR 13553) and published detailed guidance on the Department's application of section 1332 to proposed state waivers on October 24, 2018 (83 FR 53575).

Section 1341 of the ACA provides for the establishment of a transitional reinsurance program in each state to help pay the cost of treating high-cost enrollees in the individual market in the 2014 through 2016 benefit years.

Section 1343 of the ACA 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 ACA provides for, among other things, reductions in cost sharing for

EHB for qualified low- and moderate-income enrollees in silver level QHPs offered through the individual market Exchanges. This section also provides for reductions in cost sharing for American Indians enrolled in QHPs at any metal level.

Section 1411(c) of the ACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the ACA to other federal officials for verification, including income and family size information to the Secretary of the Treasury.

Section 1411(d) of the ACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the ACA for which section 1411(c) of the ACA does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f) of the ACA requires the Secretary, in consultation with the Secretary of the Treasury, the Secretary of Homeland Security, and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations.

Section 1411(f)(1)(B) of the ACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for APTC and CSRs.

Section 1411(g) of the ACA allows the use or disclosure of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs.

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act (Pub. L. 115-97, December 22, 2017) the individual shared responsibility payment has been reduced to \$0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still

relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under 45 CFR 155.305(h) or 45 CFR 156.155.

Section 1150A(a) of the Social Security Act (the Act) requires a health benefits plan or PBM that manages prescription drug coverage under a contract with a QHP issuer to provide certain prescription drug information to the Secretary at such times, and in such form and manner, as the Secretary shall specify. HHS will limit disclosure of the information disclosed by a health benefits plan or PBM under this section as required by section 1150A of the Act and may only disclose the information in a form which does not disclose the identity of a specific PBM or plan, or prices charged for specific drugs, except that for limited purposes, HHS may disclose the information to states to carry out section 1311 of the ACA. An issuer or PBM that fails to provide the information on a timely basis or that knowingly provides false information may be subject to a civil monetary penalty under section 1927(b)(3)(C) of the Act in the same manner as such provisions apply to a manufacturer with an agreement under that section.

1. Premium Stabilization Programs⁸

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

⁸ The term “premium stabilization programs” refers to the risk adjustment, risk corridors, and reinsurance programs established by the ACA. See 42 U.S.C. 18061, 18062, and 18063.

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 rate for the risk adjustment program was announced.

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

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit year and to further promote

stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the Department of Health and Human Services' Risk Adjustment Data Validation (HHS-RADV) 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 HHS-RADV 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 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 recalibration related to an update to the 2016 enrollee-level External Data Gathering Environment (EDGE) dataset.⁹

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 **Federal Register** (77 FR 17220 through 17252) and in the March 8, 2016 **Federal Register** (81 FR 12204 through 12352). This final 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 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

⁹ "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>.

as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.¹⁰

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 **Federal Register** (77 FR 17219) and in the December 22, 2016 **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 **Federal Register** (77 FR 17219) and the December 22, 2016 **Federal Register** (81 FR 94058). 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.

In the January 24, 2019 **Federal Register** (84 FR 227), we published a proposed rule outlining updates to the calibration of the risk adjustment methodology, the use of EDGE data for research purposes, and updates to HHS-RADV audits. We published the 2020 Payment Notice final rule in the April 25, 2019 **Federal Register** (84 FR 17454).

In the February 6, 2020 **Federal Register** (85 FR 7088), we published a proposed rule that included updates to the risk adjustment models' HCCs and a modification HHS-RADV error rate calculation methodology. We published the 2021 Payment Notice final rule in the May 14, 2020 **Federal Register** (85 FR 29164).

In the June 2, 2020 **Federal Register** (85 FR 33595), we published a proposed rule that

¹⁰ "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>.

proposed updates to various aspects of the HHS-RADV methodologies and processes. We published the 2020 HHS-RADV Amendments final rule in the December 1, 2020 **Federal Register** (85 FR 76979). This final rule made revisions to the HCC failure rate grouping algorithm, finalized a sliding scale adjustment in HHS-RADV error rate calculation, and a constraint on risk score adjustments for low-side failure rate outliers. The final rule also established a transition from the prospective application of HHS-RADV adjustments to apply HHS-RADV results to risk scores from the same benefit year as that being audited.

In the September 2, 2020 **Federal Register** (85 FR 54820), HHS issued an interim final rule containing certain policy and regulatory revisions in response to the COVID-19 PHE, wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year (interim final rule on COVID-19).

In the December 4, 2020 **Federal Register** (85 FR 78572), HHS issued a proposed rule containing certain policy and regulatory revisions related to the risk adjustment program (proposed 2022 Payment Notice).

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). In the December 27, 2019 **Federal Register** (84 FR 71674), we published a final rule that revised standards relating to oversight of Exchanges established by states and periodic data matching frequency.

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 ACA health

insurance market reforms that became effective in 2014 was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing those provisions 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 Market Stabilization final rule that was published in the April 18, 2017 **Federal Register** (82 FR 18346), we released further guidance related to guaranteed availability. In the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 17058), we clarified that certain exceptions to the special enrollment periods only apply with respect to coverage offered outside of the Exchange in the individual market.

4. Administrative Appeals Process Related to Federal Enforcement in Group and Individual Health Insurance Markets and Non-federal Governmental Group Health Plans

On April 8, 1997 an interim final rule with comment period was published in the **Federal Register** (62 FR 16894) that implemented the HIPAA health insurance reforms by adding 45 CFR parts 144, 146, and 148. Included in those regulations were enforcement provisions. In the June 10, 1997 **Federal Register** (62 FR 31669), we published technical corrections to these interim final rules. After gaining some experience with direct federal enforcement in some states, we determined that it was necessary to provide more detail on the procedures that will be used to enforce HIPAA when a state does not do so. On August 20, 1999, an interim final rule with comment period was published in the **Federal Register** (64 FR 45786) that provided more detail on the procedures for enforcing title XXVII of the PHS Act, as added by HIPAA, and as amended by the Mental Health Parity Act of 1996 (Pub. L. 104-204, September 26, 1996), the

Newborns' and Mothers' Health Protection Act of 1996 (Pub. L. 104-204, September 26, 1996), and the Women's Health and Cancer Rights Act of 1998 (Pub. L. 105-277, October 21, 1998), when a state does not enforce such laws. We published a final rule on November 25, 2005 in the **Federal Register** (70 FR 71020) that finalized this interim final rule, and made non-substantive amendments to the regulations detailing procedures for enforcing title XXVII of the PHS Act.

5. 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. In the July 15, 2011 **Federal Register** (76 FR 41865), we published a proposed rule with proposals 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 Small Business Health Options Program (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).

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), we set forth standards related to Exchange user fees. 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 the May 11, 2016 **Federal Register** (81 FR 29146), we published an interim final rule with 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 March 8, 2016 **Federal Register** (81 FR 12203), the final 2017 Payment Notice codified State Exchanges on the Federal platform along with

relevant requirements. 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. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period. In the May 14, 2020 **Federal Register** (85 FR 29204), the 2021 Payment Notice final rule made certain changes to plan category limitations and special enrollment period coverage effective date rules, allowed individuals provided a non-calendar year qualified small employer health reimbursement arrangement (QSEHRA) to qualify for an existing special enrollment period, and discussed plans for future rulemaking for employer-sponsored coverage verification and non-enforcement discretion for Exchanges that do not conduct random sampling until plan year 2021.

In the December 4, 2020 **Federal Register** (85 FR 78572), HHS issued a proposed rule containing certain policy and regulatory revisions related to user fees, Exchanges, and section 1332 State Innovation Waivers (proposed 2022 Payment Notice). A final rule was published in the **Federal Register** (86 FR 6138) on January 19, 2021, that addressed a subset of the policies proposed in the proposed rule. That final rule set forth provisions related to user fees for FFEs and SBE-FPs. It finalized the proposed changes related to acceptance of payments by issuers of individual market Qualified Health Plans, and clarifies the regulation imposing network adequacy standards with regard to Qualified Health Plans that do not use provider networks. It also finalized a new direct enrollment option for Federally-facilitated Exchanges and State Exchanges and implemented changes to codify in regulations certain policies related to section 1332 State Innovation Waivers.

6. Essential Health Benefits

On December 16, 2011, HHS released a bulletin¹¹ that outlined an 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.

The 2015 Payment Notice final rule, established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage. 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 National Health Expenditure Accounts (NHEA), which are calculated by the CMS Office of the Actuary. In the 2020 Payment Notice final rule, we amended the methodology for calculating the premium adjustment percentage by estimating per capita insurance premiums 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. Additionally, in response to public comments to the proposed 2021 Payment Notice, the 2021 Payment Notice final rule included a policy stating that we will finalize payment parameters that depend on NHEA data, including the premium adjustment percentage, based on the data that are available as of the publication of the proposed rule for that benefit year, even if NHEA data are updated between the proposed and final rules.

In the December 15, 2020 **Federal Register** (85 FR 81097), HHS published the final

¹¹ “Essential Health Benefits Bulletin,” December 16, 2011. Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

rule, along with the Departments of Labor and the Treasury, that finalized using the premium adjustment percentage as one alternative in setting the parameters for permissible increases in fixed-amount cost-sharing requirements for grandfathered group health plans.

7. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164) and an interim final rule was published in the September 2, 2020 **Federal Register** (85 FR 54820).

8. Quality Rating System and Enrollee Satisfaction Survey

The overall framework and elements of the rating methodology for the QRS were published in the November 19, 2013 **Federal Register** (78 FR 69418). Consistent with statutory provisions, in May 2014, HHS issued regulations at §§ 155.1400 and 155.1405 to establish the QRS and the QHP Enrollee Experience Survey display requirements for Exchanges and has worked towards requiring nationwide the prominent display of quality rating information on

Exchange websites.¹² As a condition of certification and participation in the Exchanges, HHS requires that QHP issuers submit QRS clinical measure data and QHP Enrollee Survey response data for their respective QHPs offered through an Exchange in accordance with HHS guidance, which has been issued annually for each forthcoming plan year.¹³

9. State Innovation Waivers

Section 1332(a)(4)(B) of the ACA requires the Secretaries to issue regulations regarding procedures for State Innovation Waivers. On March 14, 2011, the Departments published the “Application, Review, and Reporting Process for Waivers for State Innovation” proposed rule¹⁴ in the **Federal Register** (76 FR 13553) to implement section 1332(a)(4)(B) of the ACA. On February 27, 2012, the Departments published the “Application, Review, and Reporting Process for Waivers for State Innovation” final rule¹⁵ in the **Federal Register** (77 FR 11700) (hereinafter referred to as the “2012 Final Rule”). On October 24, 2018, the Departments issued the “State Relief and Empowerment Waivers” guidance¹⁶ in the **Federal Register** (83 FR 53575) (hereinafter referred to as the “2018 Guidance”), which superseded the previous guidance¹⁷ published on December 16, 2015 in the **Federal Register** (80 FR 78131) and provided additional information about the requirements that states must meet for waiver proposals, the Secretaries’ application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. On November 6, 2020, the Departments issued an interim final rule¹⁸ in the **Federal Register** (85 FR 71142), which revises regulations to set forth

¹² ACA; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30352 (May 27, 2014). Also see the “CMS Bulletin on display of QRS star ratings and QHP Enrollee Survey results for QHPs offered through Exchanges,” August 15, 2019. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf>.

¹³ See, for example, “Center for Clinical Standards & Quality, CMS, The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2021,” September 2020. Available at <https://www.cms.gov/files/document/quality-rating-system-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf>.

¹⁴ <https://www.govinfo.gov/content/pkg/FR-2011-03-14/pdf/2011-5583.pdf>.

¹⁵ <https://www.govinfo.gov/content/pkg/FR-2012-02-27/pdf/2012-4395.pdf>.

¹⁶ <https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf>.

¹⁷ <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

¹⁸ <https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency>.

flexibilities in the public notice requirements and post-award public participation requirements for State Innovation Waivers under section 1332 of the ACA during the COVID-19 PHE.

In the December 4, 2020 **Federal Register** (85 FR 78572), HHS issued a proposed rule under which policies announced under the 2018 Guidance would be incorporated into regulations governing State Innovation Waivers. A final rule was published in the **Federal Register** (86 FR 6138) on January 19, 2021, which adopted final regulations to incorporate certain policies announced in the 2018 Guidance regarding State Innovation Waivers.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges and the risk adjustment and HHS-RADV programs. We have held a number of listening sessions with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics, particularly risk adjustment and the direct enrollment option for FFEs and State Exchanges.

We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states, and 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 are codified in 45 CFR parts 147, 150, 153, 155, 156, 158, and 184.

The changes to 45 CFR part 147 make technical and conforming amendments regarding limited and special enrollment periods in the individual market.

The changes to 45 CFR part 150 make minor procedural changes to the requirements for administrative appeals of CMPs by health insurance issuers and non-federal governmental group health plans to align with current practices for the Departmental Appeals Board. We are

finalizing parallel changes to the requirements for administrative appeals of CMPs by QHP issuers under 45 CFR part 156, subpart J.

The changes to 45 CFR part 153 recalibrate the HHS risk adjustment models consistent with the approach outlined in the 2020 Payment Notice to transition away from the use of MarketScan® data. However, we are finalizing the policy to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating into the coefficients in the proposed rule, which would utilize enrollee-level EDGE data from 2016, 2017 and 2018 for the 2022 model recalibration, the same data years used for the 2021 model recalibration.¹⁹

We are clarifying risk adjustment reporting requirements for issuers that choose to offer premium credits, if such credits are permitted by HHS for future benefit years. In this final rule, we are also approving the requests from Alabama to reduce risk adjustment transfers by 50 percent in the individual (including catastrophic and non-catastrophic risk pools) and small group markets for the 2022 benefit year. Additionally, we clarify the process for HHS to audit issuers of risk adjustment covered plans and reinsurance-eligible plans and establish the authority for HHS to conduct compliance reviews of these issuers.

The provisions in part 153 also relate to the risk adjustment user fee for the 2022 benefit year. In this final rule, we revise the schedule for the collection of HHS-RADV charges and disbursement of payments such that these charges and disbursements will occur in the same calendar year in which HHS-RADV results are released. We also finalize provisions under part 153 to update the applicable regulations to reflect the previously established framework regarding when second validation audit (SVA) findings can be disputed or appealed, expand the conflict of interest standard for initial validation audit (IVA) Entities, and codify two previously established exemptions from the requirement to participate in HHS-RADV.

¹⁹ As detailed below, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

In part 155, we finalize the required contribution percentage for the 2022 benefit year. We amend the definition of direct enrollment technology provider and add a definition of QHP issuer direct enrollment technology provider in part 155 to recognize that QHP issuers may also use QHP issuer direct enrollment technology providers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230, and make conforming amendments to the definition of web-broker. We also codify more specific operational readiness review requirements for web-brokers and direct enrollment entities. We also amend the marketing and display requirements for direct enrollment entities, and rescind text contained in § 155.320 to implement a federal court order invalidating certain requirements in the section.

We also finalize several amendments to special enrollment period policy. Specifically, we add new flexibility to allow current Exchange enrollees and their dependents to change to a QHP of a lower metal level if they qualify for a special enrollment period due to becoming newly ineligible for APTC; allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to select a plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event; and clarify that a special enrollment period will be available when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage, and the employer contributions or government subsidies for such coverage completely cease.

In part 156, we set forth the premium adjustment percentage, maximum annual limitation on cost sharing and reduced maximum annual limitation on cost sharing for the 2022 benefit year. We also amend part 156 to establish that for the 2023 benefit year and beyond, we will publish the annual updates to the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing and required contribution percentage in guidance in January of the benefit year prior to the applicable benefit year, rather than in the applicable benefit year's annual HHS notice of benefit and payment parameters, as

long as no change to the methodologies to calculate these amounts are proposed. We finalize a methodology for analyzing the impact of preliminary values of the reduced annual maximum limitations on cost sharing on the AVs of silver plan variations. Additionally, we clarify the process for HHS to audit QHP issuers related to compliance with federal requirements for APTC, CSRs, and user fees and establish authority for HHS to conduct compliance reviews of QHP issuers to ensure compliance with federal requirements for APTC, CSRs, and user fee standards.

The changes to part 158 establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes. The changes to part 158 also remove the option for issuers to report an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality for MLR reporting and rebate calculation purposes to implement a federal court order invalidating this provision. The changes to part 158 additionally explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and filing the MLR Annual Reporting Form, and establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, the changes to part 158 allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules previously provided. Lastly, we clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS.

The addition of part 184 requires PBMs under contract with an issuer of QHPs to report prescription drug data required by section 1150A of the Act.

III. Summary of the Proposed Provisions of the HHS Notice of Benefit and Payment Parameters for 2022, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

In the December 4, 2020 **Federal Register** (86 FR 78572), we published the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates To State Innovation Waiver (Section 1332 Waiver) Implementing Regulations” proposed rule. We received a total of 542 comments in response to the proposed 2022 Payment Notice. 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 are not addressed in this final rule.

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

We first address comments regarding the publication of the proposed rule and the comment period.

Comment: Multiple commenters criticized the length of the comment period, stating that a longer comment period is necessary to allow stakeholders to review the proposed rule and provide thoughtful comments. Some commenters also expressed concern that HHS would not adequately review and consider all comments before issuing a final rule; that HHS appears to be rushing to finalize substantial changes to regulations that would hamper access to access to coverage through the Exchanges; and that HHS should defer any major policy decisions affecting access to Exchange coverage to the incoming Administration.

Response: We disagree that the comment period was not long enough to allow stakeholders to provide meaningful comments. Each year, we generally have set a 30-day comment period to accommodate issuer filing deadlines for the upcoming plan year and to avoid creating significant challenges for states, Exchanges, issuers, and other entities operating under strict deadlines related to approval of products. Moreover, we found commenters' submissions to be thoughtful and reflective of a detailed review and analysis of the proposed rule.

We further recognize the importance of federal agencies reviewing and considering all relevant comments before issuing a final rule. The comment period for the proposed rule closed on December 30, 2020. HHS has had ample time to review and fully consider comments relevant to the rules and policies finalized under this final rule.

We also disagree that the rules and policies in this final rule will hamper access to Exchange coverage. First, based on a review of the comments as a whole, we believe comments that asserted the policies in the proposed 2022 Payment Notice would hamper access to Exchange coverage were largely relevant to proposals that were finalized in the January 19, 2021 final Payment Notice, including the Exchange DE option finalized under 45 CFR 155.221(j), and the changes to the regulations governing State Innovation Waivers under 31 CFR part 33 and 45 CFR part 155.²⁰ Such comments were not focused on policies that we are finalizing in this final rule, and for reasons more fully reviewed in the preamble discussions related to specific policies in this final rule, we disagree that the rules and policies finalized in this final rule will hamper access to Exchange coverage. Further, as noted above, HHS reviewed the proposed 2022 Payment Notice and the January 19, 2021 final 2022 Payment Notice in compliance with E.O. 14009 and intends to issue a proposed rule this spring to address certain policies, including the Exchange DE option and the changes to the State Innovation Waivers regulations.

²⁰ These comments were addressed in the January 19, 2021 final 2022 Payment Notice. *See* 86 FR 6138.

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

1. Guaranteed Availability of Coverage (§ 147.104)

Section 147.104(b)(2) incorporates by reference certain Exchange special enrollment periods described in § 155.420, making those special enrollment periods applicable to non-grandfathered coverage offered in the individual market through or outside of an Exchange. We proposed amendments to § 147.104(b)(2) to clarify that paragraph (b)(2)(ii) does not apply to references in § 155.420(d)(4) (relating to errors of the Exchange), and to make a conforming amendment consistent with the proposal in § 155.420(c)(5) relating to special enrollment period availability for individuals who do not receive timely notice of a triggering event. We are finalizing these amendments as proposed.

Section 155.420(d)(4) establishes an Exchange special enrollment period for a qualified individual or their dependent if his or her enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, misconduct, or inaction of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. Section 147.104(b)(2)(ii) states that, when determining the application of a special enrollment period for individual market coverage offered outside the Exchange, a reference in § 155.420 to a “QHP” is deemed to refer to a plan, a reference to “the Exchange” is deemed to refer to the applicable state authority, and a reference to a “qualified individual” is deemed to refer to an individual in the individual market.

However, this paragraph was not intended to change the application of § 155.420(d)(4), which is specific to errors of the Exchange, not those of the applicable state authority. It would be inappropriate for the triggering event in this case to apply to errors of the applicable state authority because the state does not perform the same functions as the Exchange. For example, the state authority does not perform an enrollment function. Thus, basing the triggering event on

errors of the state is inappropriate and could create different special enrollment periods in the individual market on and off of the Exchange.

Therefore, we proposed to clarify that § 147.104(b)(2)(ii) does not apply to references in § 155.420(d)(4). As a result, issuers offering health insurance coverage in the individual market must provide a limited open enrollment period under the same circumstances as described in § 155.420(d)(4).

In addition, we proposed a conforming amendment to § 147.104(b)(4)(ii), consistent with the proposal in § 155.420(c)(5), to establish that if an individual did not receive timely notice of a triggering event described in paragraph (b)(2) or (3) of § 147.104, and otherwise was reasonably unaware that such a triggering event occurred, an issuer of non-grandfathered coverage in the individual market, whether inside or outside an Exchange, must assign the date the individual knew, or reasonably should have known, of the occurrence of the triggering event as the date of the triggering event for a special enrollment period. Consistent with §§ 147.104(b)(5) and 155.420(b), the proposed provision would allow the individual or dependent to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event or another effective date that would otherwise be available pursuant to § 155.420(b). We solicited comments on this approach. We noted that this provision would not apply for special enrollment periods in the group market, and sought comment on whether we should exclude the reference to the triggering events in § 147.104(b)(3) in the amended § 147.104(b)(4)(ii) to retain alignment of the individual and group market special enrollment periods required under § 147.104(b)(3).

We received public comments on the proposed amendments to § 147.104. Comments related to the proposal in § 155.420(c)(5) regarding when an individual does not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred are summarized and addressed in the preamble to §155.420. The following is a summary of and our response to the comments we received related to the proposal to clarify that

paragraph (b)(2)(ii) does not apply to references in § 155.420(d)(4) (relating to errors of the Exchange).

Comment: A commenter generally supported clarifying that the special enrollment period for an error of the Exchange does not extend to errors of the applicable state authority when applied market-wide in the individual market.

Response. We appreciate this comment, and we are finalizing the amendment as proposed.

B. Part 150 – CMS Enforcement in Group and Individual Markets

1. Technical Corrections

Part 150 sets forth our enforcement processes for all the requirements of title XXVII of the PHS Act with respect to health insurance issuers and non-federal governmental group health plans. We proposed to make technical corrections to multiple sections of part 150. Specifically, we proposed to remove all references to “HIPAA” and replacing them with “PHS Act” to clarify that the part 150 processes are used for enforcing not only the requirements emanating from HIPAA, but also the ACA and other legislation enacted subsequent to HIPAA. These proposed wording changes were made in the February 27, 2013 **Federal Register** final rule entitled “Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” (78 FR 13406). However, because of an oversight, some references were not updated at that time. In the proposed rule, we proposed this change to the definition of “Complaint” in § 150.103; the introductory text to § 150.303(a), as well as to §§ 150.205(e)(2); 150.213(b); 150.305(a)(1), (a)(2), (b)(1) and (c)(1); 150.311(g) and 150.313(b).

We received one comment that acknowledged these technical corrections but made no other statement about them, and we are finalizing the clarifying amendments as proposed.

2. Administrative Hearings

Additionally, we proposed certain procedural changes to part 150 sections regarding administrative hearings. The proposed changes are intended to align with the Departmental

Appeals Board's (DAB's) current practices for administrative hearings to appeal CMPs. Specifically, we proposed changes to remove requirements to file submissions in triplicate and instead require electronic filing. This change is reflected in the proposed amendments to the definition of "Filing date" in § 150.401, to the introductory text in § 150.427(a), and to the service of submission requirements captured in § 150.427(b). We also proposed amendments to several provisions in part 150 to allow for the option of video conferencing as a form of administrative hearing in part 150 in addition to the forms already allowed. To capture this flexibility, we proposed amendments to the definition of "Hearing" in § 150.401 and to the requirements outlined in § 150.419(a) related to the forms for the hearing, § 150.441(e) related to prehearing conferences, and § 150.447(a) related to the record of the hearing. Finally, we proposed to update § 150.431 to allow the Administrative Law Judge (ALJ) to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date. We proposed parallel amendments to the administrative hearings requirements under subpart J of part 156.

We received a small number of public comments on the proposed revisions to the administrative hearing requirements captured in part 150 – CMS Enforcement in Group and Individual Markets and subpart J – Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947). The following is a summary of the comments we received and our responses.

Comment: All commenters supported the availability of electronic filing for administrative appeals. However, two commenters opposed the elimination of the option to submit paper files. Those commenters specifically noted that consumers might not be comfortable with technology or have access to electronic means to file administrative appeals.

Response: We appreciate the commenters' concerns about eliminating paper filing as an option. However, the administrative appeals procedures in part 150 apply to plans and issuers;

they are separate and apart from consumer appeals processes.²¹ In addition, the proposed changes were intended to update the administrative hearing regulations in order to align with the DAB's current practices and did not make changes to existing practices.

The DAB's Civil Remedies Division, which handles the administrative hearings on CMPs under part 150 and subpart J of part 156, fully transitioned from paper to electronic filing to increase administrative efficiency and provide greater access and convenience to parties. However, a party may request a written waiver from the requirement of using DAB E-File. See Civil Remedies Division Procedures § 6, *available at* <https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-alj/procedures/filing-and-service-of-written-material>. If a waiver is granted, the party may file documents by U.S. mail or an express delivery service. *Id.*

Therefore, because the changes were intended to reflect the DAB's current practices that incorporate a written waiver process, and because these changes do not affect the consumer appeals processes, we are finalizing the revisions as proposed.

Comment: All commenters supported allowing video conferencing as a form of hearing. One commenter also noted that the system should include third party interpreters, whether foreign language or sign language.

Response: We appreciate the commenter's accessibility concerns regarding the video conferencing system. While it is not specifically noted in the administrative hearing regulations in part 150 and subpart J of part 156 language, the DAB complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. The DAB provides free aids and services to people with disabilities, including sign language interpreters, and provides free language services to people whose primary language is not English, including qualified interpreters. Instructions for requesting these services are available here: <https://www.hhs.gov/about/agencies/dab/about-dab/nondiscrimination->

²¹ See, for example, 45 CFR 155.355.

notice/index.html. The DAB's Civil Remedies Division also provides a written nondiscrimination notice with similar instructions to individual parties in every case.

Because DAB's current system already allows for these means of access and these changes align our regulations with the DAB's current practices, we are finalizing the revisions as proposed.

Comment: Two commenters requested that HHS adopt specific timeframes for the ALJ to communicate next steps for an administrative hearing in order for consumers to better prepare for the hearing and to avoid delays in the process. The regulation, as proposed, allows the ALJ to communicate next steps either in the acknowledgement of a request for a hearing or on a later date.

Response: We understand commenters' concerns that the lack of a specified time period for response from the ALJ may allow for some uncertainty related to the timing for the proceedings. However, as previously noted, the administrative appeals procedures in part 150 and subpart J of part 156 apply to plans and issuers; they are separate and apart from consumer appeals processes. Further, the proposed changes were intended to update the regulations in order to reflect the DAB's current practices and did not make changes to existing practices for administrative appeals by plans and issuers. Therefore, we are finalizing the revisions as proposed.

C. Part 153 – Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

Subparts A, B, D, G, and H of part 153, provide standards for administering the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the ACA 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.²² In accordance with § 153.310(a), a state that is approved or conditionally approved by the Secretary to operate

²² 42 U.S.C. 18063.

an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.²³ We did not receive any requests from states to operate risk adjustment for the 2022 benefit year; therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2022 benefit year.

We proposed changes to our approach for identifying the 3 benefit years of enrollee-level EDGE data that would be used for purposes of the annual recalibration of the HHS risk adjustment models. We also proposed modeling updates to improve the models' predictive power for certain subgroups of enrollees, as well as proposed changes to the enrollment duration factors for the adult models, and we proposed to continue a pricing adjustment related to Hepatitis C drugs. We proposed to allow states to submit multi-year requests for reductions to transfer calculations under the state payment transfer formula and we outlined the 2022 benefit year reduction requests submitted by Alabama. Additionally, we proposed to clarify risk adjustment reporting requirements for issuers that choose to offer premium credits, if permitted by HHS for future benefit years, and to codify a materiality threshold for EDGE discrepancies. We proposed the risk adjustment user fee for the 2022 benefit year and to codify in regulation the previously established exemptions from HHS-RADV requirements for issuers with only small group market carryover coverage in the benefit year being audited and for sole issuers in a state market risk pool during the benefit year being audited. We also proposed to revise the schedule for the collection of HHS-RADV charges and disbursement of payments such that these charges and disbursements would occur in the same calendar year in which HHS-RADV results are released. Finally, we proposed to shorten the discrepancy reporting windows during HHS-RADV, clarify and expand the conflict of interest standards applicable to initial validation audit (IVA) entities, and update the risk adjustment regulations to more clearly reflect the previously established limitations on the ability to dispute or appeal SVA findings and clarify the timeframe for HHS-RADV appeals.

²³ Also see 42 U.S.C. 18041(c)(1).

1. 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 HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and 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.²⁴ 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 CSR 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) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the state transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable state market risk pool. 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.

a. Updates to Data Used for Risk Adjustment Model Recalibration

Consistent with the approach outlined in the 2020 Payment Notice to no longer rely upon MarketScan® data²⁵ for recalibrating the risk adjustment models, we proposed to continue to recalibrate the risk adjustment models for the 2022 benefit year using only enrollee-level EDGE

²⁴ For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult risk adjustment models. See, for example, 83 FR 16941.

²⁵ 84 FR 17463 through 17466.

data. However, rather than using 2017, 2018 and 2019 enrollee-level EDGE data, we proposed to use the 2016, 2017, and 2018 enrollee-level EDGE data (the same years' data used to recalibrate the 2021 risk adjustment models) to recalibrate the risk adjustment models for the 2022 benefit year. We also proposed to continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2022 benefit year model recalibration. We are finalizing these policies as proposed.

Previously, we used the three most recent years of MarketScan[®] data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. Then, starting with the 2019 benefit year, we began transitioning from using the MarketScan[®] data to using the enrollee-level EDGE data to recalibrate the risk adjustment models. The 2021 benefit year was the first year that we recalibrated the risk adjustment models using 3 years of enrollee-level EDGE data.²⁶ Specifically, for the 2021 benefit year, we used the 2016, 2017, and 2018 benefit years of enrollee-level EDGE data to recalibrate the risk adjustment models. During prior recalibrations, we implemented an approach that used blended, or 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. In some prior years, this approach resulted in reliance on data that could not be incorporated into the coefficients until after the publication of the applicable benefit year's Payment Notice, because the associated data was not available in time to incorporate into the models in time for publication in the Payment Notice.²⁷ For example, due to the timing of the proposed 2021 Payment Notice, we were unable to incorporate the 2018 benefit year enrollee-level EDGE data into the proposed coefficients in the proposed 2021 Payment Notice, and instead included draft coefficients in the proposed rule reflecting only 2016 and 2017 benefit years' enrollee-level EDGE data.²⁸ We were also unable to

²⁶ 85 FR 29173 through 29175.

²⁷ See, for example, the 2018 Payment Notice final rule, 81 FR 94058; and the 2021 Payment Notice final rule, 85 FR 29173 through 29175.

²⁸ See 85 FR 7097 through 7098 and 7104 through 7112.

incorporate the 2018 benefit year enrollee-level EDGE data in the final coefficients in the 2021 Payment Notice; therefore, consistent with § 153.320(b)(1)(i), we released the final 2021 benefit year coefficients in guidance after publication of the 2021 Payment Notice.²⁹ We followed a similar approach in other benefit years when we were unable to incorporate the most recent year of available data in the applicable benefit year's Payment Notice.³⁰

Some commenters to the proposed 2021 Payment Notice expressed concern about when the final blended coefficients would be available, asking that final coefficients be made available earlier. Having the risk adjustment coefficients for the upcoming benefit year available earlier allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year. Commenters offered suggestions for ways HHS could provide final coefficients sooner. Stakeholders submitted similar comments in prior years when the final coefficients were released in guidance after publication of the applicable benefit year's Payment Notice.³¹ While in the initial years of risk adjustment and implementation of the 2014 federal market reforms (such as guaranteed availability and community rating), the markets underwent rapid changes in which the relative impact of using the most recent available data for recalibrating the risk adjustment models may have been more pronounced. However, in recent years, HHS has shifted from recalibrating the risk adjustment models using a blend of the three most recent years of large group market data to using data collected entirely from the risk adjustment population (enrollee-level EDGE data). This change has resulted in coefficients that better reflect underlying market conditions, and the markets have continued to mature and stabilize in the years following implementation of the risk adjustment program and other 2014

²⁹ See 85 FR 29173 through 29175. Also see <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>, <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>.

³⁰ See, for example, the 2018 Payment Notice rule, 81 FR 94084. Also see <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>.

³¹ See, for example, 81 FR 94084 through 94085.

federal ACA reforms, thereby reducing the relative impact of the most recent data year on model coefficients. As a result, we continued to consider these comments and we proposed to change our approach for identifying the 3 most recent years of enrollee-level EDGE data that would be used to recalibrate the risk adjustment models. Previously, we used the 3 most recent years of data that were available in time for publication in the final rule or soon thereafter in guidance. However, beginning with the 2022 benefit year, we proposed to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the data in the draft recalibrated coefficients published in the proposed rule and we proposed to not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data became available for incorporation. The purpose of the proposed change was to respond to stakeholders' request to provide the proposed coefficients in the proposed rule and to release the final coefficients earlier, while continuing to use the 3 most recent consecutive years of enrollee-level EDGE data available to recalibrate the risk adjustment models. We explained that we believe this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration. As proposed, the approach also would continue to use actual data from issuers' individual and small group (or merged) market populations, as well as maintain year-to-year stability in risk scores as the recalibration would continue to use at least 2 years of enrollee-level EDGE data that were used in the previous year's models.³²

For these reasons, we proposed to use 2016, 2017, and 2018 benefit years' enrollee-level EDGE data for the 2022 benefit year model recalibration. We sought comment on our proposal to determine coefficients for the 2022 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data and our

³² As detailed earlier, the 2022 benefit year recalibration would rely on the same 3 years of enrollee-level EDGE data that were used in the 2021 benefit year. For the 2023 benefit year and beyond, the recalibration would rely on 2 years of the enrollee-level data that were used in the prior year.

proposed approach to identify the 3 most recent years of data available for the annual recalibration of the risk adjustment models moving forward. Additionally, we sought comment on whether we should instead maintain the approach that would use the 2017, 2018, and 2019 benefit years' data to recalibrate the risk adjustment models for the 2022 benefit year.

We also noted that the coefficients could change if the proposed recalibration policies, or other proposed modeling parameters, were not finalized or were modified in response to comments. In addition, we explained that, consistent with § 153.320(b)(1)(i), if we were unable to finalize the final coefficients in time for the final rule, we would publish the final coefficients for the 2022 benefit year in guidance soon after the publication of the final rule.

We received public comments on the proposed updates to data used for risk adjustment model recalibration and the proposed 2022 benefit year model recalibration approach. The following is a summary of these comments and our responses.

Comment: Many commenters supported the inclusion of the actual coefficients that would apply to risk adjustment models for that benefit year in the applicable benefit year's payment notice. Some commenters supported the proposal to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating in the proposed recalibrated coefficients published in the proposed rule and to not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available for incorporation. Some of these commenters stated that providing the recalibrated coefficients earlier in the process will promote stability, better meet the goals of the risk adjustment program, and more closely align with issuer pricing cycles for individual and small group health insurance coverage.

Other commenters did not support the proposed approach and recommended instead to maintain the approach used in previous years, which would lead to the use of the 2017, 2018, and 2019 benefit years enrollee-level EDGE data for model recalibration for the 2022 benefit year. These commenters stated that incorporating newer data was more important than having the

model coefficients earlier, with several commenters expressing concern that the proposed approach would rely on older data that would not include the most up-to-date experience and would not accurately reflect the reality and actuarial risk of the applicable benefit year.

One commenter that opposed the proposed approach stated that because issuers are required to submit all claims information to their respective EDGE servers by April 30th following the end of a benefit year, there should be enough time to include the most recent year's enrollee-level EDGE data in the applicable benefit year's proposed payment notice. The commenter expressed the view that if the final coefficients are known by the end of March, issuers can properly incorporate risk adjustment coefficients for rate-setting for the following year. However, another commenter stated that they preferred having the final coefficients sooner, by the end of January, and expressed support for the proposed approach if the final coefficients incorporating the most recent year of data that becomes available are not expected to be ready within that timeframe.

Response: We are finalizing the proposals to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the data in the recalibrated coefficients published in the proposed rule and that we will not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available. We agree with commenters that this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration using actual data from issuers' individual and small group (or merged) market populations.

Additionally, we clarify that while we may collect the most recent plan year's EDGE data prior to the publication of the proposed rule, the data are often not available in time for incorporation into the proposed coefficients until much later. This is because the process to prepare enrollee-level EDGE data for incorporation into risk adjustment model recalibration is

rigorous and requires time for analysis and data quality checks. Therefore, we believe utilizing the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for inclusion in the coefficients in the proposed rule promotes stability while ensuring data quality and avoids the delays in publication of the coefficients that stakeholders have continued to raise concerns about in comments on the annual payment notices. This policy will allow HHS to provide proposed coefficients in the proposed rule that reflects the same underlying data as will be utilized for the final rule. This approach will minimize changes between the proposed and final coefficients that result from differences in data years, particularly in cases where the risk adjustment models and any accompanying proposed updates are finalized without changes. As noted earlier, in the initial years of risk adjustment and implementation of the 2014 federal market reforms, the markets underwent rapid changes in which the relative impact of using the most recent data for recalibrating the risk adjustment models may have been more pronounced. However, in recent years, HHS has shifted from recalibrating the risk adjustment models using a blend of the three most recent years of large group market data to using data collected entirely from the risk adjustment population (enrollee-level EDGE data). This change has resulted in coefficients that better reflect underlying market conditions, and the markets have continued to mature and stabilize, thereby reducing the relative impact of the most recent data year on model coefficients.

This policy will also allow us to continue to use the 3 most recent consecutive years of enrollee-level EDGE data available to recalibrate the risk adjustment models. It also continues to use actual data from issuers' individual and small group (or merged) market populations and maintains year-to-year stability in risk scores as the recalibration would continue to use at least 2 years of enrollee-level EDGE data that were used in the previous year's models. Finally, since this approach could allow us to finalize the coefficients earlier, it could allow issuers more time to incorporate this information when pricing their plans for the upcoming benefit year.

The proposed coefficients that were published in the proposed rule reflected the other proposed risk adjustment model specification changes (that is, inclusion of a two-stage model specification in the adult and child models; addition of severity and transplant indicators interacted with HCC counts factors in the adult and child models; modification to the enrollment duration factors in the adult models; and removal of the current severity indicator and enrollment duration factors in the adult models). However, based on our decision to not finalize those proposed model specification changes at this time as described below, the proposed coefficients outlined in the proposed rule are not being finalized. Instead, as discussed in more detail below, we will continue to apply the current risk adjustment model specifications (that is, the enrollment duration factors for the adult models and the severity illness indicators in the adult models that were finalized in the 2021 Payment Notice will continue to apply for the 2022 benefit year, with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year). The final coefficients outlined below reflect the use of the 2016, 2017, and 2018 benefit years enrollee-level EDGE data to develop blended, or averaged, coefficients from the 3 years of separately solved models, as proposed, and the maintenance of the current adult model severity indicators and enrollment duration factors, with trending adjustments made to reflect the 2022 benefit year.³³ In response to comments expressing concern about the use of older years of data, we note that, similar to previous years, we used 3 years of blended data to develop the 2022 risk adjustment models with certain adjustments to that data, such as trending the data to reflect the applicable benefit year.³⁴ These adjustments are necessary because recalibration efforts have always used data from prior benefit years to project a future benefit year. As such, even if we adopted the alternative approach suggested by some commenters and used the 2017, 2018 and 2019 data for the 2022 benefit year recalibration, the recalibration data

³³ As detailed later in the preamble, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

³⁴ We previously discussed trending and standardized benefit design parameters in the risk adjustment models in the “March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper,” March 24, 2016, available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

would still need to be trended forward to project for the applicable benefit year. We believe this approach of incorporating adjustments to the enrollee-level EDGE data to project the coefficients for the applicable benefit year is appropriate and consistent with the use of prior benefit years data for model recalibration, and strikes the appropriate balance between the policy desire to provide the coefficients earlier in the pricing cycle for the upcoming plan year and the concerns about recalibration data not reflecting the most up-to-date experience. After our continued consideration of stakeholder requests for earlier release of the risk adjustment coefficients, along with the comments on the proposed 2022 Payment Notice, we are finalizing the proposals to use the 3 most recent consecutive years of enrollee-level EDGE data available in time for incorporating the data in the recalibrated coefficients published in the proposed rule and that we will not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available. The final coefficients outlined below for the 2022 benefit year reflect the use of the 2016, 2017, and 2018 benefit years enrollee-level EDGE data for recalibration purposes.³⁵

Comment: One commenter sought clarification on the reasoning and implications for using the 2016, 2017, and 2018 enrollee-level EDGE data.

Response: We proposed changes to how we identify the 3 most recent consecutive years of enrollee-level EDGE data for the annual recalibration of the HHS risk adjustment models to respond to stakeholders' request to provide the coefficients earlier. This approach allows HHS to avoid delays in publication of the coefficients, which will allow issuers more time to incorporate this information when pricing their plans for the upcoming benefit years. While this approach will utilize a set of data that is one year older than what we have used in previous years, we will continue to project the coefficients to reflect estimated costs for the applicable benefit year. We believe that this approach will promote stability while ensuring data quality and avoid the delays

³⁵ As detailed later in the preamble, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

in publication of the coefficients. It also continues to use actual data from issuers' individual and small group (or merged) market populations and maintains year-to-year stability in risk scores as the recalibration would continue to use at least 2 years of enrollee-level EDGE data that were used in the previous year's models. Therefore, we are finalizing the use of the 3 most recent consecutive years of enrollee-level EDGE data that is available to HHS in time for incorporation in the proposed coefficients in the annual proposed payment notice.

Comment: One commenter noted that the stated advantages for publishing final coefficients earlier has similarly applied in prior years as well, and HHS could always publish the final Payment Notice earlier. This commenter also stated that the changed approach in the proposed rule disrupts issuers' settled expectations, namely, that issuers had assumed a continuation of past practice, through which the proposed rule's coefficients are updated in the final rule to include new data.

Response: As stated in the proposed rule, we proposed changes to our approach to identify the 3 most recent consecutive years of enrollee-level EDGE data that would be used for the annual recalibration of the risk adjustment models in response to stakeholder feedback. HHS has continued to receive numerous comments from stakeholders that expressed concerns about the timing for release of the model coefficients and asked that final coefficients be made available earlier. The approach we used in previous benefit years sometimes resulted in delays in publication of the final coefficients until after the publication of the applicable benefit year's Payment Notice,³⁶ because the associated data was not available in time to incorporate into the models in time for publication in the Payment Notice.

We considered the potential disruption to issuers' settled expectations and we explicitly sought comments from stakeholders on whether to finalize the proposed approach, or whether we should instead maintain the approach of using the 2017, 2018, and 2019 benefit years' data to

³⁶ For example, the final 2021 benefit year risk adjustment model coefficients were published in guidance after the final annual benefit and payment parameters. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>

recalibrate the risk adjustment models for the 2022 benefit year. As part of our analysis, we considered that it is appropriate for HHS to consider changes to program parameters through notice-and-comment rulemaking, including the proposed changes to the approach for the annual model recalibration. We further note that even if we were to maintain the approach suggested by commenters to utilize the 2017, 2018, and 2019 benefit years, changes in the underlying data would attenuate the relative impact of the most recent benefit year data on risk adjustment coefficients. This is because the coefficients also incorporate changes to the risk adjustment methodology for the applicable benefit year, updated plan design parameters, and certain other adjustments to the data, such as trending the data to reflect the applicable benefit year. Finally, as noted above, in the initial years of risk adjustment and implementation of the 2014 federal market reforms, the markets underwent rapid changes, however, in recent years the markets have continued to mature and stabilize. We believe the approach finalized in this rule will provide stability and easier price prediction for issuers for the 2022 benefit year and beyond. It is an appropriate and reasonable response to comments submitted by stakeholders over the years asking HHS to reevaluate these issues and find a way to release the coefficients earlier to align with issuer pricing cycles.

Comment: One commenter who supported the proposed approach noted that there may be circumstances that result in changes to the risk adjustment models between the date the proposed rule is published and the date the final rule is published, and recommended that if HHS makes any final modifications to the coefficients, they should be issued no later than the release of the final payment notice for the applicable benefit year.

Response: We agree that the coefficients could still change between the proposed and final rules. There are various reasons that this could happen, such as the proposed recalibration policies (or other proposed modeling parameters) not being finalized, or those parameters are modified in response to comments. As stated above and described more fully below, our decision not to finalize the proposed changes to the risk adjustment model specifications and other

proposed model updates demonstrates how changes between the proposed and final rule can impact the risk adjustment coefficients.

While we intend to make the proposed and final coefficients available as early as possible, we did not propose to delete and are still retaining the flexibility under § 153.320(b)(1)(i) that permits HHS to release the final coefficients in guidance after publication of the final rule. Consistent with prior years where we have invoked this flexibility, we intend any subsequent publication of final coefficients would occur either in the final rule or in guidance published soon after the publication of the final rule.

Comment: Several commenters recommended that we consider whether utilizing the 2020 benefit year enrollee-level EDGE data for future years' risk adjustment model calibration would be appropriate in light of the COVID-19 pandemic.

Response: We did not propose to use 2020 benefit year enrollee-level EDGE data as part of the annual recalibration of the risk adjustment models for the 2022 benefit year. However, we understand commenters' questions about the 2020 benefit year enrollee-level EDGE data and its use for recalibration of future benefit years' risk adjustment models. We intend to carefully review the 2020 benefit year enrollee-level EDGE data as it becomes available to assess the potential impact of the COVID-19 pandemic and consider whether it should be used for recalibration of the HHS risk adjustment models in future benefit years. Additionally, we note that our decision to use the 2016, 2017, and 2018 benefit years data for the 2022 benefit year model recalibration provides an additional year to evaluate the 2020 benefit year enrollee-level EDGE data and assess the implications for using 2020 benefit year enrollee-level EDGE data for risk adjustment model recalibration.³⁷ If necessary, we will propose any needed changes related to risk adjustment model recalibration through rulemaking published in advance of the applicable benefit year.

³⁷ Consistent with the approach finalized in this rulemaking, the earliest the 2020 enrollee-level EDGE data would be used for model recalibration is the 2024 benefit year.

After consideration of the comments on these proposals, we are finalizing the approach to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the data in the recalibrated coefficients published in the proposed rule and to not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available. As a result, we will use 2016, 2017, and 2018 enrollee-level EDGE data to recalibrate the 2022 risk adjustment models.³⁸

b. Risk Adjustment Model Updates

Beginning with the 2022 benefit year, we proposed several updates to the risk adjustment models. These proposed updates include changes to the specifications for the adult and child models and updates to the enrollment duration factors in the adult models to improve the models' predictions. We also proposed to continue the market pricing adjustment for Hepatitis C drugs that has been in place since the 2020 benefit year.

We are not finalizing the proposed model specification changes and enrollment duration factor updates or the accompanying removal of the current severity illness indicators and enrollment duration factors in the adult models at this time. Therefore, the current adult model severity illness indicators and enrollment duration factors, with trending adjustments made to reflect the 2022 benefit year, will apply for the 2022 benefit year without the proposed specification changes. We are finalizing and will continue the market pricing adjustment for the Hepatitis C drugs that has been in place since the 2020 benefit year.

(1) Changes to the model specifications

Beginning with the 2022 benefit year, we proposed to modify the adult and child models specifications to improve prediction for enrollees at both the low and highest ends of expected expenditures. The current HHS-HCC models are estimated by a weighted least squares

³⁸ As detailed later in the preamble, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

regression.³⁹ The dependent variable is annualized simulated plan liability expenditures, and the weight is the person-specific sample eligibility fraction. The effective outcome is that the models predict per member per month (PMPM) expenditures.

As described in the 2021 Payment Notice, the current HHS-HCC models, which are linear models, underpredict plan liability for enrollees without HCCs (enrollees with low expected expenditures) and underpredict plan liability for enrollees with the highest HCC counts (enrollees with high expected expenditures).⁴⁰ In the 2021 Payment Notice, we described options that we were considering to address these issues, such as adding a non-linear term or HCC counts factors to the risk adjustment models.⁴¹ For the non-linear model option, we considered adding a coefficient-weighted sum of payment HCCs raised to a power that could be interpreted as a measure of overall disease burden. For the HCC counts model option, we considered adding eight indicator variables corresponding to 1 to 8-or-more payment HCCs, similar to the CMS-HCC risk adjustment counts models used for Medicare Advantage.⁴² We have further evaluated the performance of these options, their potential for improved prediction, and considered other alternatives to improve the HHS risk adjustment models' prediction.

Our initial analyses showed that the non-linear and HCC counts models would yield considerable gains in predictive accuracy in the adult models across several subgroups when compared to the current linear models.⁴³ We tested both the HCC counts and non-linear models' impact on the adult silver risk adjustment models and found that the enrollees in the lowest cost deciles had better predictive ratios under either the HCC counts or non-linear model specification than under the current linear model specification. However, both models had shortcomings that

³⁹ See, for example, 78 FR 15420 and Section 3.7 of the "March 31, 2016 HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper," March 24, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

⁴⁰ 85 FR 29188 and 29189.

⁴¹ Ibid.

⁴² "Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model," December 20, 2018. Available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part1.pdf>.

⁴³ 85 FR 7101 through 7104.

prompted us to consider alternate model options to improve the predictive power of the current HHS risk adjustment models. For the HCC counts model, we noted that we were concerned that the presence of counts across all HCCs may promote gaming in coding practices. We explored ways to assure modeling convergence across all metals and data years, and found that the non-linear models did not consistently converge in all testing scenarios, and that convergence could not reliably be assured without constraining model factors and revising those techniques with each metal and data year model run. Therefore, we continued to explore additional types of model specifications refinements that could balance the goals of improving the models' prediction with mitigating modeling complexity and gaming concerns. Specifically, as described later in this section, we explored a two-stage specification with additional weighting in the second stage based on the inverse capped prediction from the first stage ("two-stage specification"), a specification with HCC counts included for a small number of severity and transplant HCCs ("interacted HCC counts factors"), and an approach combining the two-stage specification with the interacted HCC counts factors.

For the two-stage specification, we explored calibrating the adult and child models in two stages: in the first-stage estimation, the model coefficients would be estimated using the current model specifications; and in the second stage, we would re-estimate the model weighted by the reciprocal of the predicted values of relative expenditures from the first step estimation with the same model specification.⁴⁴ The first stage of the weighted estimation method involved a linear regression (weighted by the person-specific eligibility fraction of the number of months enrolled divided by 12) of simulated plan liability on age-sex factors, payment HCC factors, the enrollment duration factors,⁴⁵ and RXCs for the adult models. For the child models, the first

⁴⁴ This weighted approach is similar to the weighted least squares approach with the weight equal to the reciprocal of the estimated variance that is often used to correct for heteroskedasticity. However, in our proposed approach, we would use the reciprocal of predictions from the first step as weights to correct for underprediction of low-valued coefficients.

⁴⁵ We proposed to remove and replace the enrollment duration factors in the adult models in the proposed rule, but we are not finalizing the proposed changes to the enrollment duration factors in this final rule and will apply the current enrollment duration factors of up to 11 months, with trending adjustments made to reflect the 2022 benefit year, in the adult models for the 2022 benefit year.

stage of the weighted estimation method involved a linear regression of simulated plan liability on age-sex factors and payment HCC factors. The second stage involved using the reciprocal of first-stage predictions as weights for a second linear regression.⁴⁶ To stabilize the weights for the second stage estimation, we imposed lower and upper bound caps on the first-stage predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. We tested various caps for the weights based on the distribution of costs, and found these lower and upper bound caps achieved better prediction on average. This approach has the material effect of weighting the healthier enrollees, who represent a majority of enrollees in the individual and small group (including merged) markets but who are underpredicted by the current models, more heavily so that the statistical model predicts their expenditures more accurately. On the other hand, this approach systematically underweights, and therefore underpredicts, very expensive enrollees. However, the capped weighting approach would mitigate the potential to underpredict at the high end for expensive enrollees, as well as any possible low-end overprediction. In our consideration of this option, we tested various weights, including reciprocals of the square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of these alternative weighting functions.

We also explored how the addition of severity and transplant indicators interacted with HCC counts, wherein an indicator flagging the presence of at least one severity or transplant payment HCC is being interacted with counts of the enrollee's payment HCCs.⁴⁷ The goals for this approach were to: (1) address the non-linearity in costs between enrollees with no or very low costs and enrollees with high costs; (2) empirically incorporate the cost impact of multiple

⁴⁶ Under the proposed two-stage specification and interacted HCC counts model described later in this section, we proposed to remove and replace the severity illness indicators in the adult risk adjustment models with the proposed interacted HCC counts factors in the adult and child models. However, we are not finalizing these proposed model specification changes in this final rule and will continue to apply the current severity illness indicators in the adult models for the 2022 benefit year.

⁴⁷ For HCCs in a group, the group is counted at most once. These groups of HCCs in the risk adjustment models are typically detailed in the Tables 6 and 7 of the HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software.

complex diseases; and (3) mitigate the gaming concerns with the HCC counts model. We tested different types of severity and transplant indicators interacted with HCC counts with the goal of improving prediction for enrollees with the highest costs and multiple HCCs to counter balance the reciprocal prediction weights that relatively underpredicted costs for these enrollees. For this approach, we assessed the HCCs for enrollees with extremely high costs, and HCCs that were being underpredicted in the current risk adjustment models. We found that many of the HCCs that were flagged as being under-predicted were those HCCs that indicated severe illness , such as the transplant HCCs, and other HCCs related to severity of disease; therefore, we considered dropping the current severity illness indicators in the adult models and replacing them with severity and transplant indicators interacted with HCC counts factors in the adult and child models. Table 3 in the proposed rule⁴⁸ listed the HCCs that were selected for the severity and transplant indicators for the adult and child models for purposes of exploring this option. The severity and transplant indicators were then interacted with HCC counts factors, which are described below.

The purpose of adding severity and transplant indicators interacted with HCC counts factors is to account for the fact that costs of certain HCCs rise significantly when they occur with multiple other HCCs. To mitigate the incentive to upcode multiple HCCs, we only increased incremental risk scores in the presence of at least one of the selected HCCs in the severity or transplant indicator groups in Table 3 in the proposed rule. That is, an adult or child enrollee would have to have at least one HCC in the “severity” or “transplant” indicator groups in Table 3 in the proposed rule to receive the interacted HCC counts coefficient toward their risk score.

Under this approach, when an adult or child enrollee has a severity indicator HCC in Table 3 in the proposed rule, the enrollee’s risk score would include the sum of: (1) severity

⁴⁸ See 85 FR at 78593.

HCC variable coefficient;⁴⁹ and (2) applicable severity HCC counts variable coefficient. The HCC counts factors, which indicate the counts of all payment HCCs for an enrollee with at least one HCC, interacted with the severity indicator in Table 3 in the proposed rule, range from one, two, to 10+ payment HCCs (1, 2, ..., 10+) for the adult models, and from one, two, to 5, then 6 or 7, and 8+ payment HCCs for the child models. To implement the severity indicator HCC counts factors and further explore this option, we removed the current severity illness indicators in the adult models, and added severity indicator interacted HCC counts variables for the adult and child models.

For the transplant-related HCCs within the severity indicator HCC counts in Table 3 in the proposed rule, we found separating out transplant HCCs into their own additional indicator to interact HCC counts factors improved prediction for these high-cost enrollees. Therefore, for the transplant HCCs, we created a separate transplant indicator to interact with payment HCC counts of 4, 5, 6, 7, or 8+ for the adult models, and a single indicator variable of payment HCC counts of 4+ for the child models. For example, an adult enrollee with a transplant HCC 34 “Liver Transplant Status/Complications” in the transplant indicator group and three other payment HCCs received the following factors toward their risk score in the adult models: (1) the four coefficients for their individual HCCs (the three non-transplant HCCs and the HCC 34 transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC counts of 4 coefficient.⁵⁰ The child model operated similarly. For a child enrollee with a transplant HCC in the transplant indicator group and three other payment HCCs, the following was used to calculate the enrollee’s risk score: (1) coefficients for all four HCCs, (including the transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC counts of 4 coefficient.

⁴⁹ This is in addition to the HCC coefficients for any other HCCs that the enrollee has, as well other risk adjustment factors that the enrollee has (such as demographic factors). If an enrollee has no severity HCCs the severity count interaction term coefficients are not applicable.

⁵⁰ This is in addition to other risk adjustment factors that the enrollee has (such as demographic factors).

As an alternative, we explored interacting the HCC counts factors with each selected severity and transplant HCC, but found it was sufficient to interact the HCC counts factors with a variable indicating the presence of at least one of the selected HCCs in each group to improve prediction for enrollees with these HCCs. We also explored different combinations of HCC counts to identify the counts factors for both indicator groups in the adult and child models that provided the best balance of reasonable sample sizes and relative cost differences between each counts factor. More specifically, in the adult models, we found that starting with 4+ HCCs for the transplant interacted factors improved predictions of enrollees at the very high end in terms of risk and cost and ending at 8+ HCCs instead of 10+ HCCs addressed the small sample sizes of enrollees with a transplant and 9 or more payment HCCs. For the child models, we found having one variable for 4+ payment HCCs provided more stable estimates as compared to separate variable for each payment HCC above that number, given the smaller sample sizes for children than those for adults.

Lastly, we tested combining these specifications into an alternative approach that incorporated both the two-stage specification and the severity and transplant indicators interacted HCC counts factors described above for the HHS adult and child models. We found this combined approach generally improved prediction for enrollees at both the low and highest ends of expected expenditures. Specifically, even though we found that the age-sex factors and some HCCs might have slightly worse predictive ratios under the proposed combined approach than the current linear models, we found that this combined approach improves predictive ratios in comparison to the current models in each decile of predicted plan liability. We also found that this combined approach improves R-squared in comparison to the current model and that even though the coefficients for the model factors that are most impacted by the combined approach (the age-sex factors and the severity and transplant HCCs) would be changing under the 2022 benefit year models compared to the 2021 benefit year models, the average enrollee's adult risk score in the recalibration sample in the silver metal level only increased slightly between 2021

benefit year models to 2022 benefit year models. Therefore, we proposed to modify the HHS risk adjustment model specifications for the adult and child models by combining a two-stage specification and adding interacted HCC counts factors beginning with the 2022 benefit year. For the two-stage specification, we proposed calibrating the adult and child models in two stages. The first stage of the weighted estimation method would involve a linear regression of simulated plan liability on age-sex factors and payment HCC factors for the adult and child models, with the addition of the enrollment duration and RXCs factors for the adult models. The second stage would use the reciprocal of prediction as weights from the first step as a second stage linear regression. To stabilize the weights from the first stage predictions, we proposed lower and upper bound caps on the predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. This two-stage specification would be combined with the severity and transplant indicators from the interacted HCC counts factors. For the severity indicator group, we proposed to add separate count factors for one to 10+ payment HCCs counts factors (1, 2, ..., 10+) for the adult models and one to 5, 6 or 7, and 8+ payment HCCs (1, 2, ...5, 6 or 7, 8+) for the child models. The proposed HCCs that would flag the severity indicator are listed in Table 3 of the proposed rule.⁵¹ For the transplant HCCs, we proposed to incorporate variables for 4 to 8+ payment HCCs (4, 5, 6, 7, 8+) for the adult models and one variable for 4+ payment HCCs for the child models. All variables, including the severity and transplant indicators interacted in the interacted HCC counts factors, would be included in both stages of the regressions. We proposed to incorporate these model specification updates beginning with the 2022 benefit year HHS risk adjustment adult and child models. We also proposed to remove the current severity illness indicators in the adult models beginning with the 2022 benefit year.

We sought comment on these proposals, including on the HCCs selected for flagging as severity and transplant indicators listed in Table 3 of the proposed rule such as whether we should include HCC 18 Pancreas Transplant in the transplant indicator group, and the

⁵¹ See 85 FR at 78593.

alternatives described above. We also requested comment on whether we should pursue both the interacted HCC counts factors and the two-stage specification beginning with the 2022 benefit year (as proposed), if we should implement one of the two approaches beginning with the 2022 benefit year (and if so, which one), or if we should wait to implement the proposed changes that combines the proposed model specification updates until the 2023 benefit year.

We are not finalizing the risk adjustment model specification changes as proposed at this time, but will further consider potential changes that could increase the predictive power of the HHS risk adjustment models. We also are not finalizing the accompanying proposals to remove the current severity illness indicators in the adult models; those factors, as finalized in the 2021 Payment Notice, will continue to apply to the 2022 benefit year adult models with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year.⁵²

We received public comments on the proposed updates to the model specification changes. The following is a summary of these comments and our responses.

Comment: Many commenters opposed the proposed risk adjustment model specification changes and wanted to know more about the specific impacts of the proposed risk adjustment model specification changes. Many of these commenters were concerned that HHS did not give stakeholders adequate information or time to assess the model specification changes, while some stated that the model specification changes were unexpected and not fully reviewed with stakeholders in advance of them being proposed for implementation. These commenters suggested that, consistent with recent efforts to update risk adjustment data validation, HHS should release a White Paper and conduct listening sessions to provide stakeholders with the opportunity to evaluate the impact of the changes and provide HHS with feedback in advance of pursuing such changes through rulemaking. Some commenters generally wanted additional

⁵² See the Severity Factors listed in Table 1.

analyses or more specificity about the model changes while others requested specific types of analyses.

Some commenters that opposed the proposed model specification changes were concerned the changes added complexity to the models and would hinder issuers' ability to price accurately, resulting in higher premiums. Other commenters recommended that HHS collect data to estimate the impact of the proposed model specification changes on risk adjustment transfers before finalizing them. Another commenter recommended evaluating model performance at the plan level instead of the enrollee level using the plan liability risk score predictive ratios because the transfer formula operates at the plan and rating level, wanting HHS to collect data to do this type of analysis.

A few commenters were concerned that the proposed model specification changes would reduce the quality of coverage available to consumers and would threaten the market's ability to support robust competition. One of these commenters recommended that we reconsider the goal of reducing under prediction for enrollees with low spending, because this commenter believed that plans that disproportionately attract sick enrollees tend to attract enrollees who are higher-than-average risk based on characteristics not captured in risk adjustment, and that therefore risk adjustment should underpay for low spending enrollees relative to payment for higher-risk enrollees.

However, other commenters supported our proposed model specifications changes. These commenters tended to support improving the predictive power of the risk adjustment models and were concerned about the potential for plans to lose money on enrollees with no HCCs under the current model specifications, discouraging issuers from enrolling healthier enrollees and resulting in excessive risk adjustment payments. One of these commenters reported engaging in their own analysis of the proposed model specification changes and found that they achieved HHS's goals of improving the models' prediction while mitigating modeling complexity and gaming concerns.

Response: After consideration of comments on these proposals, we are not finalizing the proposed model specifications changes at this time and will retain the existing severity illness indicators in the adult models. We intend to continue to consider potential changes that could increase the predictive power of the HHS risk adjustment models in future rulemaking for future benefit years. While we believe stakeholders had sufficient time and adequate information to evaluate these model specifications, as reflected in the detailed comments received on these proposals, we understand stakeholders' desire for additional analyses on these types of model specification changes prior to implementing them in the risk adjustment models. We also appreciate issuers' desire for additional time to prepare for these types of model specification changes and to consider how to price for these model specification changes. While we are limited in our ability to evaluate model performance at the plan level because the enrollee-level EDGE data does not include plan level information, to test the performance of the risk adjustment models for subgroups, we calculate the expenditure ratio of predicted to actual weighted mean plan liability expenditures by subgroup, also referred as the predictive ratios.⁵³ Regardless, we agree that more time, and some additional analysis, would help stakeholders further review these changes, help issuers price more accurately, and prevent the introduction of inadvertent volatility in the market(s) as a result of new model specifications. It will also help inform whether refinements to these proposals or other options would be appropriate to meet the overall policy goal of improving the models' predictive power for the lowest cost and highest cost enrollees and developing a model that most accurately captures risk for those with and without HCCs. For these reasons, we are considering releasing a technical paper to provide further assessment of potential changes to the risk adjustment models and additional analysis of options to improve the prediction of the risk adjustment models. In addition, if we decide to

⁵³ March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting. Discussion Paper. March 24, 2016. <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

pursue these changes, or other options, to improve the predictive power of the models for future benefit years, we would propose such updates through notice-and-comment rulemaking.

Comment: Some commenters were concerned that the two-stage specification would over-fit the model or would worsen the fit along other dimensions. One of these commenters questioned the basis for the weighting function chosen in the two-stage specification noting that it appeared to be arbitrary and recommended that HHS consider using industry-standard methods to test modeling choices for overfitting and then publish the results of these tests when explaining modeling decisions. This commenter cautioned against an overemphasis on improving model performance in the absence of both a sound theoretical basis for changes and an independent data set to confirm an increase in accuracy. Another commenter recommended that HHS not finalize the proposed risk adjustment model specifications since the two-stage specification does not mitigate the under-prediction of health care costs for enrollees with the highest number of HCCs. One commenter was concerned that the proposed two-stage specification would not predict future costs.

Response: We are not implementing the proposed model specifications at this time. However, in response to comments, we note that as part of our assessment of the proposed model specification changes we tested for overfitting of the models by running predictive ratios on the separate validation samples for both the child and adult models. While the sample sizes are smaller in the child models than the adult models, leading to greater fluctuations for the child models, we found that the predictive ratios in the separate validation samples showed no material difference relative to predictive ratios in the estimation sample. Thus, we did not find empirical concerns with respect to overfitting of the models with the proposed model specification changes.

As previously mentioned, we believe it is appropriate to continue to analyze the two-stage specification and interacted HCC counts factors and are considering releasing a technical paper to provide our further assessment of potential changes to the risk adjustment models that

could include these model specification changes or other options. In addition, we would pursue adoption of any of these model specification changes, or other options, for future benefit years through notice-and-comment rulemaking.

Comment: Some commenters were concerned about the potential for small sample sizes for the interacted HCC counts model specification. These commenters tended to be concerned that the number of enrollees could drop significantly as the interacted HCC counts go up, which could lead to erratic interacted HCC counts factors coefficients, and had concerns that the proposed rule had some large changes between coefficients and coefficients going from negative to positive for a given count across metal levels. One commenter was concerned that the low sample sizes at higher HCC counts associated with larger coefficients could increase the models' volatility, making it more difficult for issuers to price coverage. Other commenters were concerned that the interacted HCC counts model specification could incentivize unwanted gaming in coding practices by issuers. One commenter that supported the adoption of the interacted HCC counts model specification was concerned that the interacted HCC count model change would encourage issuers to invest additional resources in diagnosis coding. Another commenter did not believe that using interacted HCC counts factors would create an opportunity for gaming, and did not understand how using a full HCC counts model specification would result in gaming opportunities either.

Response: As noted previously, after consideration of comments, we are not finalizing the proposed model specification updates, including the interacted HCC counts factors, at this time. While we believe that the proposed rule provided stakeholders with adequate information to evaluate these model specifications, we recognize that stakeholders could benefit from further analysis and additional time to analyze the structure of the proposed interacted HCC counts factors. In response to the commenters expressing concerns about negative coefficients under the proposed interacted HCC counts factors, we note that when an enrollee has a severity indicator

HCC, the enrollee's risk score would include the sum of: (1) severity HCC variable coefficient⁵⁴; and (2) applicable severity HCC counts variable coefficient. This means that even though many of the interacted HCC counts factors outlined in the proposed rule were negative coefficients, the net combined impact of the HCC coefficients and the interacted "severity" or "transplant" HCC counts coefficient, to the enrollee's risk score would be positive.⁵⁵

In developing the proposed interacted HCC counts factors, we also considered sample sizes of the various interacted HCC counts factors. We analyzed multiple years of enrollee-level EDGE data and we chose the model specifications that grouped all of the HCC counts interacted with individual severity and transplant HCCs into two sets of aggregated factors to maximize sample size, reduce concerns of overfitting the model, and reduce the number of factors being added to the models. The resulting sample size for the proposed interacted HCC counts factors were consistent with the sample size for individual HCCs in the risk adjustment models. Furthermore, by limiting the proposed interacted HCC counts factors to certain severity and transplant HCCs, we believe that the interacted HCC counts factors would restrict the scope for coding proliferation in accordance with the principles of risk adjustment.⁵⁶

As discussed in the 2021 Payment Notice, we considered using a counts model specification where all HCCs were subject to the counts model specifications, but, as stated in

⁵⁴This is in addition to the HCC coefficients for any other HCCs that the enrollee has, as well other risk adjustment factors that the enrollee has (such as demographic factors). If an enrollee has no severity HCCs the severity count interaction term coefficients would not be applicable.

⁵⁵ To further illustrate, we can consider a male enrollee age 63 in silver metal level who has diabetes but no other risk markers. Using the proposed coefficients in the proposed rule, his proposed model predicted cost would be: $0.343 \text{ (age-sex estimate)} + 0.262 \text{ (diabetes HCC estimate)} = 0.605$.

If he develops sepsis, which is an interacted "severity" HCC, his predicted cost would be:

$0.605 + 9.394 \text{ (sepsis HCC)} + -5.824 \text{ (interacted severity HCC counts factor for 2 total HCCs estimate)} = 4.175$.

If this enrollee also develops heart failure, his predicted cost would further rise:

$0.605 + 9.394 + 1.874 \text{ (heart failure HCC)} + -4.526 \text{ (interacted severity HCC counts factor for 3 total HCCs)} =$

7.347 . As can be seen in these illustrative examples, although the interacted "severity" HCC counts factors are negative, the interacted "severity" HCC counts factor rise with the enrollee's total number of HCCs, increasing the enrollee's total predicted cost as his number of HCC diagnoses increases. In fact, the increasing risk scores with each additional HCC is consistent with the current models and predictions are higher for enrollees with many HCCs under the interacted counts specification than under the current model specification.

⁵⁶ We have described our principles for risk adjustment in various documents, but a complete list of them is available in the March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper. March 24, 2016. Pages 12-13, <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

the proposed rule, we were concerned that the presence of counts across all HCCs may promote gaming in coding practices. This was our reasoning for investigating an interacted HCC counts model specification to find a way to get the benefits afforded by the HCC counts model while mitigating the potential for gaming. The proposed interacted HCC counts factors would have made changes primarily to the HCCs most associated with underprediction of high-cost cases in the model and would have only applied to less than two percent of the population thereby reducing the concern about additional coding incentives in comparison to a general HCC counts model.

We agree that stakeholders will benefit from additional time to analyze the proposed factors that we presented in the proposed rule to understand the incremental effects of the interacted HCC counts factors and consider the associated coding incentives. After consideration of comments received on these proposals, we are not finalizing the proposed model specification changes or the removal of the current severity illness indicator factors in the adult models at this time. However, we intend to continue to consider changes that can increase the predictive power of the HHS risk adjustment models in rulemaking for future benefit years and also intend to provide stakeholders with further information and additional analysis on potential model specifications changes.

Comment: One commenter believed that inclusion of the interacted HCC counts factors appears to be a discriminatory practice.

Response: We are not finalizing the policy at this time, but we disagree. The interacted HCC counts factors proposed to be added to the HHS risk adjustment models are not discriminatory. HHS takes very seriously our obligation to protect individuals from discrimination. Consistent with section 1343 of ACA, the HHS-operated risk adjustment program reduces the incentives for issuers to avoid higher-than-average risk enrollees, such as those with chronic conditions, by using charges collected from issuers that attract lower-than-average risk enrollees to provide payments to health insurance issuers that attract higher-than-

average risk enrollees. The proposed interacted HCC counts factors would help predict enrollee risk better for certain subpopulations. Therefore, we do not believe the inclusion of the interacted HCC counts factors is a discriminatory practice and as stated above, the proposed inclusion of interacted HCC counts would reduce the under-prediction of the highest cost cases and the under-prediction of the low-risk enrollees, thereby helping to mitigate the potential for adverse selection by improving the predictive power of the HHS risk adjustment models for these enrollees.

Comment: One commenter wanted HHS to consider using more metrics than R-squared statistics to assess the proposed model specification changes, such as mean absolute prediction error or predictive ratios for subsets of the population. Another commenter was concerned that the proposed revisions to incorporate interacted HCC counts factors and modify the enrollment duration factors alone would result in worse model performance among lower-cost deciles even if they result in higher R-squared values overall. Another commenter wanted to ensure that HHS's modeling was taking into account the high-cost risk pool component of the HHS risk adjustment methodology.

Response: While we did assess R-squared statistics for the performance of our proposed model specification changes, our primary metric to evaluate performance and the proposed changes was predictive ratios by subgroup. We found that the proposed interacted HCC counts and the proposed revised enrollment duration factors (discussed in the below section) improved the model performance for the low-end deciles even without the inclusion of the proposed two-stage specifications. We intend to continue to assess model performance in future benefit years, and we will also consider assessing the mean absolute prediction error along with predictive ratios and R-squared statistics as we continue to assess potential model specification changes in the future. We also confirm that the annual recalibration of the HHS risk adjustment models, including both the development of final coefficients listed in this rule and the proposed coefficients reflecting the proposed model specification changes in the proposed rule, accounts

for the costs covered by the high-cost risk pool component of the HHS risk adjustment methodology.^{57,58}

Comment: Some commenters focused on the proposed timeline for implementation of the proposed model specification changes. Some of these comments were opposed to implementing the model specification changes in 2022 and some supported delaying implementation to the 2023 benefit year (or beyond). One commenter wanted all model specification changes completed within one benefit year and then recommended limiting model changes in future benefit years to provide year-to-year stability. Another commenter supported applying the proposed model specification changes beginning with the 2022 benefit year risk adjustment models.

Response: As noted previously in this rule, after consideration of comments on these proposals, we are not finalizing the proposed model specifications at this time and are retaining the current severity illness indicator factors in the adult models. We agree that stakeholders would benefit from having additional analysis and time to consider these changes. Therefore, we intend to provide stakeholders with additional analysis and further information about potential model specification changes and will continue to consider changes that can increase the predictive power of the HHS risk adjustment models. Any such changes would be pursued through rulemaking for future benefit years. As part of our continued analysis of potential future changes, we intend to consider ways to balance the desire to adopt refinements to improve the predictive power of the models with the need to promote stability.

c. Changes to the Enrollment Duration Factors

In the proposed rule, we proposed changes to the enrollment duration factors in the adult risk adjustment models to improve the prediction for partial year enrollees with HCCs. After

⁵⁷ Beginning with the 2018 benefit year risk adjustment recalibration, we incorporated the high-cost risk pool parameters in our recalibration of the models by truncating 40 percent of costs above \$1 million in our dataset used to simulate plan liability. See, for example, 81 FR 94058 at 94082.

⁵⁸ See, for example, the proposed 2022 Payment Notice, 85 FR at 78586 (In announcing the proposed coefficients, noting that “(t)he 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.”)

consideration of comments received, we are not finalizing the proposal to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, or the addition of new monthly enrollment duration factors of up to 6 months that would only apply for enrollees with payment HCCs in the adult models. For the 2022 benefit year, we will continue to apply the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year. See Table 1. Similar to the other proposed model specification changes outlined elsewhere in this rule that we are not finalizing in this rule, we intend to continue to analyze potential changes to the enrollment duration factors to improve model prediction for partial year enrollees with HCCs.

As described in the proposed 2021 Payment Notice, we have been considering potential adjustments to the enrollment duration factors and previously analyzed the current factors using the 2016 and 2017 enrollee-level EDGE data.⁵⁹ We explored heterogeneity (variations) of costs for partial year enrollees in the presence of certain diagnosis codes, by market (individual or small group),⁶⁰ and under various enrollment circumstances, such as enrollment beginning later in the year or ending before the end of the year. Our preliminary analysis of 2017 enrollee-level EDGE data found that the current enrollment duration factors are driven by enrollees with HCCs. That is, partial year enrollees with HCCs had higher PMPM expenditures on average as compared to full year enrollees with HCCs. On the other hand, partial year enrollees without HCCs were not significantly different in PMPM expenditures compared to full year enrollees without HCCs. In the 2021 Payment Notice, we also explained that our preliminary analysis found that, in comparison to the effect of the presence of HCCs on enrollment duration factors, enrollment timing (for example, enrollment at the beginning of the year compared to enrollment after open enrollment period, or drop in enrollment before the end of the year) did not appear to

⁵⁹ See 85 FR 7103 and 7104.

⁶⁰ In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

affect PMPM expenditures on average. While we did not make changes to the enrollment duration factors in the 2021 Payment Notice, we stated that we were considering eliminating the monthly enrollment duration factors up to 11 months and replacing them with monthly enrollment duration factors up to 6 months for enrollees with HCCs. We also stated that we intended to review the trends observed in our preliminary analysis using an additional year's data before proposing changes.

Since the publication of the 2021 Payment Notice, we have reassessed enrollment duration factors for adults using the 2018 benefit year enrollee-level EDGE data. The additional data year's findings were consistent with our prior finding that partial year enrollees without HCCs do not have PMPM expenditures that are significantly different compared to full year enrollees without HCCs. Therefore, beginning with the 2022 benefit year, we proposed to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, and add new monthly enrollment duration factors of up to 6 months to the adult models that would only apply for enrollees with payment HCCs. Under the proposal, there would be no enrollment duration factors for adult enrollees without payment HCCs starting with the 2022 benefit year adult models. As part of this analysis, we also considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between markets on average once we implemented the proposed enrollment duration factors of up to 6 months for adult enrollees with payment HCCs. Therefore, we did not propose enrollment duration factors for the adult models by market type at this time. We also proposed to continue to incorporate enrollment duration factors only in the adult models.⁶¹ We solicited comment on the changes to the enrollment duration factors for the adult models. We also sought comment on whether we should implement these model changes starting with the 2022 benefit

⁶¹ As explained in the 2021 Payment Notice proposed rule, we found that partial year enrollees in the child models did not have the same risk differences as partial year enrollees in the adult models and they tended to have similar risk to full year enrollees in the child models. In the infant models, we found that partial year infants had higher expenditures on average compared to their full year counterparts; however, the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors and did not have a meaningful impact on the general predictive power of the infant models. See 85 FR 7103 and 7104.

year, whether we should delay implementation until the 2023 benefit year, or whether we should create the enrollment duration factors for different lengths, such as up to 9 months of enrollment, instead of up to 6 months.

We are not finalizing the proposal to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, or to add new monthly enrollment duration factors of up to 6 months that would only apply for enrollees with payment HCCs in the adult models. We intend to consider proposing changes that increase the predictive power of the HHS risk adjustment models model in the future, including with respect to improving model prediction for partial year enrollees with HCCs. We received public comments on the proposed changes to the adult model enrollment duration factors. The following is a summary of the comments we received on these proposals and our responses.

Comment: Many commenters were opposed to the new enrollment duration factors for up to 6 months for adult enrollees with a payment HCC. These commenters wanted additional analysis on the new enrollment duration factors, such as further evaluation of the new enrollment duration factors in a White Paper or dialogue during stakeholder listening sessions. Other commenters supported the new enrollment duration factors (of up to 6 months for adult enrollees with a payment HCC). These commenters believed that the new enrollment duration factors would capture adverse selection related to partial year enrollment and were concerned that plans are unable to recover premiums for the foreseeable additional costs that result from partial year enrollees.

A few commenters opposed the new enrollment duration factors because they believed that the current enrollment duration factors that apply to all adult enrollees help to offset under-prediction of healthy enrollees in the risk adjustment models and that the proposed enrollment duration factors would undermine this offset by only applying to adult enrollees with an HCC. Other commenters believed that the current enrollment duration factors helped mitigate some potential under-prediction issues in the small group market.

Some commenters wanted HHS to implement the proposed enrollment duration factors changes beginning with the 2022 benefit year. Other commenters recommended delaying implementation of the proposed enrollment duration factor changes to the 2023 benefit year, asking that HHS provide additional analysis on the enrollment duration factor changes in the interim to assist issuers with pricing their plans to reflect these changes. One commenter wanted HHS to implement the proposed enrollment duration factor changes now so that carriers are not deterred from enrolling people seeking coverage during special enrollment periods with millions of people losing employer-sponsored insurance due to COVID-19.

Response: Similar to the other proposed model specification changes, we are not finalizing the revisions to the enrollment duration factors at this time and will consider proposing changes that increase the predictive power of the HHS risk adjustment models in the future. For the 2022 benefit year, we will continue to apply the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models with trending adjustments made to project the data used to develop the factors forward to reflect the 2022 benefit year. We recognize that stakeholders would benefit from additional analysis and time to assess these or other potential changes to the enrollment duration factors. We also see value in making any changes to the enrollment duration factors at the same time as other model specification changes under consideration to address the under-prediction of no HCC enrollees. This approach to aligning the enrollment duration factors changes with the timing of other potential model specification changes targeted to improve the predictive power of the models would support a balanced approach to addressing the over-prediction of no HCC enrollees with partial year enrollment at the same time that we address the under-prediction of no HCC enrollees (with full or close to full year enrollment) in the risk adjustment models. We note that the current enrollment duration factors still compensate plans for partial year enrollees, and therefore, already help mitigate any disincentive to enroll partial-year enrollees.

Therefore, we are also not finalizing the proposed changes to the enrollment duration factors at this time and will continue to apply the current 11 enrollment duration factors of up to 11 months, with trending adjustments made to reflect the 2022 benefit year, for all enrollees in the adult models. In addition, we are considering releasing a further analysis of potential changes to the risk adjustment models that could include updates to the adult model enrollment duration factors.

Comment: Some commenters wanted HHS to consider whether enrollment duration factors should be tied to certain HCCs, believing that not all HCCs contribute equally to the coefficient for enrollees with the one month enrollment duration factor and wanting us to constrain the enrollment duration factor to a subset of HCCs driving the high one-month enrollment duration factor coefficient value. One commenter recommended HCC specific enrollment duration factors for maternity HCCs be finalized for the 2022 benefit year. Another commenter recommended the creation of enrollment duration factors up to 9 months of enrollment for adult enrollees with HCCs (instead of up to 6 months for enrollees with HCCs, as proposed).

Response: While we are not finalizing changes to the adult model enrollment duration factors at this time, as part of our analysis of the enrollment duration factors, we did review the most common HCCs in the 2018 enrollee-level EDGE data for one month enrollees. We found that the most common HCCs for one month adult enrollees are also common HCCs in the enrollee-level EDGE data. However, our main concern with the suggestion to tie enrollment duration factors to certain HCCs or specific to maternity HCCs is that many new factors would have to be added to the models to create HCC-specific enrollment duration factors, adding an additional level of complexity and potential instability to the models.

We also note that as part of our analysis of potential changes to the adult model enrollment duration factors, we considered creating factors for adult enrollees with HCCs for up to 9 months and tested this alternative model specification using 2018 enrollee-level EDGE data.

We found that the estimated coefficients for the factors between 6 and 9 months were small and in some cases negative. We also did not find meaningful improvement in the predictive ratios when using enrollment duration factors up to 9 months. For these reasons, we proposed using enrollment duration factors of up to 6 months for enrollees with HCCs. However, as detailed above, we are not finalizing the proposed changes to the enrollment duration factors or the accompanying removal of the current enrollment duration factors in the adult models at this time.

Comment: Some commenters wanted enrollment duration factors by market type or wanted HHS to consider whether the individual and small group markets should have market specific risk adjustment model coefficients. Some of these commenters were concerned that the proposed enrollment duration factors were created to address a partial year enrollment issue that primarily exists in the individual market and had concerns about making changes to the enrollment duration factors in the small group market which has non-calendar coverage that can somewhat artificially create partial year enrollees. Other commenters had concerns about removing the previous enrollment duration factors for the small group market, believing that the previous enrollment duration factors mitigate the disconnect between the calendar year for EDGE claims and the renewal year for the small group market, which is often not on the calendar year. One commenter was concerned that eliminating the existing enrollment duration factors would be destabilizing for any market where an issuer may obtain a higher percentage of new small employer business relative to other competitors. Other commenters were concerned about issuers' ability to capture HCCs in the small group market, especially when plan renewal can occur in December, limiting the amount of time that issuers would have to collect diagnosis codes for the applicable benefit year of risk adjustment even though the issuer would have claims for December. Another commenter was concerned about small issuers and Medicaid issuers being able to effectively capture HCCs from churning enrollees.

Response: As discussed in the proposed rule, we considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between

markets on average once we implemented the proposed enrollment duration factors of up to 6 months for adult enrollees with payment HCCs. Therefore, we did not propose and are not finalizing market-specific enrollment duration factors. Furthermore, we are not aware of any evidence that would indicate that various types of issuers (for example, issuers of various sizes, Medicaid issuers, private market issuers) are unable to capture HCCs for partial year enrollees.

After consideration of the comments received, we are not finalizing the proposed revisions to the enrollment duration factors at this time. For the 2022 benefit year, we will continue to apply the current 11 enrollment duration factors of up to 11 months, with trending adjustments made to reflect the 2022 benefit year, for all enrollees in the adult models.

d. Pricing Adjustment for the Hepatitis C Drugs

For the 2022 benefit year models, we proposed to continue applying the market pricing adjustment to the plan liability associated with Hepatitis C drugs that has been in place beginning with the 2020 benefit year final risk adjustment models.⁶² We are finalizing the pricing adjustment for Hepatitis C drugs as proposed.

As explained in the proposed rule, we continue to believe this market pricing adjustment is necessary and appropriate to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim, and therefore, make the risk adjustment transfer results more favorable for the issuer. We previously stated that we intended to reassess this pricing adjustment with future benefit years' enrollee-level EDGE data.⁶³ However, in alignment with the proposal to use the same 3 years of enrollee-level EDGE data for the 2022 benefit year model recalibration as those used for the

⁶² 84 FR 17463 through 17466.

⁶³ 85 FR 29185.

2021 benefit year, we proposed to continue making a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the 2022 benefit year models.⁶⁴ We noted that we intend to reassess this pricing adjustment in future recalibrations with additional years of enrollee-level EDGE data. We sought comment on this proposal.

We received public comments on the proposed continuation of the market pricing adjustment for Hepatitis C drugs for the 2022 benefit year. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the continuation of the pricing adjustment for Hepatitis C drugs stating that it would more accurately reflect the average cost of treatment in the risk adjustment models, ensure enrollees can continue to receive incremental credit for having both the Hepatitis C RXC and HCC, and account for the introduction of new Hepatitis C drugs. One commenter recommended HHS clarify the data source and approach used to constrain the Hepatitis C RXC coefficient, and cautioned against reducing the coefficient more than the expected decrease in cost. One commenter similarly recommended HHS reassess this adjustment on an ongoing basis to ensure the coefficient is not constrained beyond the expected decrease in the cost of the drugs.

Response: In response to comments, we note that we continue to assess trends in the enrollee-level EDGE data as well as monitor for developments that would impact expectations for pricing for Hepatitis C drugs to ensure that the adjustments are reasonable and are not reduced below the expected decrease in cost. We reassessed the pricing adjustment for Hepatitis C drugs for the 2022 benefit year model recalibration using the most recent year of data (2019 enrollee-level EDGE data) and found the costs for Hepatitis C drugs continued to show a significant decline when compared to the costs in the 2018 enrollee-level EDGE data. Therefore,

⁶⁴ The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

we continue to believe that it is necessary and appropriate to use a pricing adjustment for Hepatitis C drugs for the 2022 benefit year since the data used to recalibrate the risk adjustment models, which does not include the 2019 enrollee-level EDGE data, does not reflect the average cost of Hepatitis C treatments applicable to the 2022 benefit year when newer and cheaper Hepatitis C drugs will be available. Because the cost of these drugs were reflected in the 2016, 2017 and 2018 enrollee-level EDGE datasets without a pricing adjustment to plan liability, the Hepatitis C RXC in the 2022 benefit year based on this data could overcompensate issuers and incentivize them to encourage overprescribing practices to favorably impact their risk adjustment transfers (increase their payment or decrease their charge). The pricing adjustment finalized here helps avoid perverse incentives, and leads to Hepatitis C RXC coefficients that better reflect anticipated actual 2022 benefit year plan liability associated with Hepatitis C drugs. We intend to continue to reassess this pricing adjustment in future benefit years' model recalibrations using additional years of available enrollee-level EDGE data.

Comment: One commenter agreed with HHS's stated concern that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim. In contrast, another commenter questioned the view that issuers are gaming risk adjustment by encouraging providers to prescribe particular treatments when they are unnecessary.

Response: Due to the changing cost of these drugs reflected in the data used for recalibration purposes (that is, the 2016, 2017 and 2018 enrollee-level EDGE data), without a pricing adjustment to plan liability, issuers could be overcompensated for the Hepatitis C RXC in the 2022 benefit year and could be incentivized to "game" risk adjustment or encourage overprescribing practices. More specifically, the absence of a pricing adjustment could incentivize some issuers to influence provider prescribing patterns because the drug claim could trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim. This would lead to the calculation of inflated risk scores and would make the risk

adjustment transfer results more favorable for the issuer (that is, increase a payment or decrease a charge). To avoid perverse incentives to influence overprescribing behavior, we are finalizing a market pricing adjustment for Hepatitis C drugs. It is an appropriate and necessary adjustment in light of the cost of the drugs reflected in the 2016 through 2018 enrollee-level EDGE data and the introduction of newer and lower cost Hepatitis C drugs that will be available in the 2022 benefit year. We intend to continue to reassess whether this pricing adjustment is needed for future benefit years.

Comment: One commenter expressed concern about issuers potentially gaming risk adjustment based on when the Hepatitis C drug prescription is filled. The commenter noted that because HHS-operated risk adjustment operates on a calendar year basis an issuer could receive credit for a prescription filled in December of Year 1 and receive credit for the same individual for a prescription filled in January of Year 2, potentially double-dipping in risk adjustment. The commenter recommended we modify the EDGE server requirements to mandate the tracking of the days supply of each prescription fill and scale the coefficient by the percentage of a recommended therapeutic regime supplied over the course of the year to reduce the possibility of gaming.

Response: While some stakeholders have expressed concern about timing for filling Hepatitis C prescriptions, we have previously analyzed the potential for issuers to game HHS-operated risk adjustment by encouraging consumers to refill prescriptions for the treatment for Hepatitis C in December and January and have not found clear evidence that this type of behavior is occurring. However, as part of our consideration of the comments received on this proposal, we revisited this analysis using more recent data and found similar results. Therefore, based on our analysis and continued study of this issue, we do not believe modifications to HHS-operated risk adjustment program or EDGE server requirements are needed at this time. However, we will continue to monitor usage trends to assess whether modifications to the Hepatitis C pricing adjustment or the adoption of other safeguards to prevent potential double-

dipping are warranted in the future. We further note that the proposed suggestions by the commenter – to modify EDGE server requirements or scale the coefficient – would introduce burden and complexity to the HHS-operated risk adjustment program. If we determine pursuit of these types of measures is warranted for future benefit years, we would need to weigh these disadvantages against any potential benefits.

Comment: Some commenters asked HHS to monitor the market and introduction of new expensive therapies and treatments, such as gene therapy drugs, and incorporate them into the risk adjustment model factors due to the anticipated high costs of these drugs and associated services. The comments noted that the costs of very new, high cost treatments will not be reflected in prior year enrollee-level EDGE data. One commenter noted that that while the high-cost risk pool, which compensates plans for enrollees with claims over \$1 million, is helpful, there may be a need for something more specific in the risk adjustment model to account for these costs.

Response: We did not propose to update the risk adjustment model factors to reflect the costs of gene therapy drugs in the proposed rule and are not finalizing such updates in this rule. We recognize that the data used to recalibrate the risk adjustment models are lagged by several benefit years and cannot account for the costs of new, expensive gene therapy drugs that are expected to be available by the 2022 benefit year. Thus, we considered whether to include any gene therapy drugs in the risk adjustment models for the 2022 benefit year as a separate RXC or an additive HCC. In considering these options, our primary concern was that we do not have adequate data on these drugs to create a separate RXC or an additive HCC for the 2022 benefit year and we are concerned with the ability to obtain data of an adequate population size given the limited use of these drugs.

We note that if an enrollee in an issuer's risk adjustment covered plan has claims for gene therapy or other expensive treatments, that enrollee would be eligible for the high-cost risk pool payments if claims for that enrollee are over \$1 million. We intend to assess the use of gene

therapy drugs as additional data become available and consider whether model updates are warranted to address their anticipated costs in the future.

Comment: One commenter wanted to ensure the required ancillary services associated with pre-exposure prophylaxis (PrEP) use were being incorporated into risk adjustment. Another commenter expressed concern that some prescription drug codes (Descovy®) that are used for PrEP would map to an RXC in the risk adjustment models while others prescription drug codes used for PrEP would not.

Response: In the 2021 Payment Notice, we incorporated PrEP as a preventive service in the simulation of plan liability in the risk adjustment adult and child models with zero cost sharing after careful analysis of preventive drugs that are recommended at grade A or B by the United States Preventive Services Task Force (USPSTF). We are again incorporating the costs of PrEP in this same manner in the 2022 risk adjustment models to give issuers credit at the preventive services level for the costs of these drugs. We also considered treating ancillary services for PrEP as preventive services in risk adjustment model recalibration. However, we found that many of the recommended PrEP ancillary services (such as, HIV screenings) already qualify as preventive services and as such are already calibrated at 100 percent plan liability; therefore, no updates were made to capture these services in the simulation of plan liability in the adult and child models. However, we will continue to consider whether additional PrEP ancillary services should be treated as preventive services for risk adjustment model recalibration for future benefit years.

We further note that we also continuously assess the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment models. As a result of this on-going assessment, we make quarterly updates to the RXC Crosswalk to ensure drugs are being mapped to RXCs where appropriate, including adding and removing new and old drugs. In response to the comments regarding the potential different treatment of PrEP drugs in risk adjustment, we note that in January 2021, we announced that consistent with our treatment

of other PrEP drugs, Descovy® would be removed from RXC 1 in the final Benefit Year (BY) 2020 Do it Yourself (DIY) update, released in April 2021, since it can be used as a preventive drug.⁶⁵ Enrollees that use Descovy® (or other PrEP drugs) in combination with other HIV treatment drugs will still receive credit for RXC 1. We will continue these types of reviews in the future.

After consideration of the comments we received on this proposal, we are finalizing the proposal to continue the market pricing adjustment for Hepatitis C drugs.

e. List of Factors to be Employed in the Risk Adjustment Models (§ 153.320)

The final 2022 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2016, 2017, and 2018 enrollee-level EDGE data, consistent with the policies finalized in this rulemaking, are shown in Tables 1 through 6.⁶⁶ 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.⁶⁷ Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC-HCC interactions, severity interactions, and enrollment duration coefficients. Table 2 contains the 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 models' maturity and severity categories, respectively.

⁶⁵ HHS-Developed Risk Adjustment Model Algorithm “Do It Yourself (DIY)” Software Instructions for the 2020 Benefit Year (April 15, 2021 Update), available at <https://www.cms.gov/files/document/cy2020-diy-instructions04132021.pdf>.

⁶⁶ As detailed below, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

⁶⁷ As detailed below, we did not propose and are finalizing any changes to the high-cost risk pool parameters for the 2022 benefit year. Therefore, we are maintaining the \$1 million threshold and 60 percent coinsurance rate.

TABLE 1: Adult Risk Adjustment Model Factors for 2022 Benefit Year

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21-24, Male	0.128	0.086	0.049	0.020	0.019
	Age 25-29, Male	0.128	0.086	0.049	0.019	0.017
	Age 30-34, Male	0.159	0.109	0.065	0.029	0.027
	Age 35-39, Male	0.187	0.129	0.077	0.034	0.033
	Age 40-44, Male	0.222	0.157	0.099	0.051	0.049
	Age 45-49, Male	0.251	0.181	0.117	0.062	0.060
	Age 50-54, Male	0.333	0.253	0.181	0.119	0.117
	Age 55-59, Male	0.372	0.283	0.204	0.135	0.132
	Age 60-64, Male	0.418	0.320	0.232	0.155	0.152
	Age 21-24, Female	0.217	0.151	0.093	0.047	0.045
	Age 25-29, Female	0.236	0.165	0.103	0.053	0.051
	Age 30-34, Female	0.306	0.226	0.155	0.097	0.095
	Age 35-39, Female	0.372	0.283	0.204	0.139	0.136
	Age 40-44, Female	0.425	0.326	0.238	0.163	0.160
	Age 45-49, Female	0.433	0.329	0.234	0.153	0.149
	Age 50-54, Female	0.470	0.366	0.269	0.185	0.181
	Age 55-59, Female	0.445	0.339	0.241	0.156	0.152
	Age 60-64, Female	0.446	0.337	0.235	0.147	0.144
Diagnosis Factors						
HCC001	HIV/AIDS	1.520	1.379	1.282	1.212	1.210
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	7.045	6.891	6.847	6.864	6.867
HCC003	Central Nervous System Infections, Except Viral Meningitis	5.927	5.857	5.833	5.835	5.835
HCC004	Viral or Unspecified Meningitis	5.072	4.918	4.820	4.718	4.716
HCC006	Opportunistic Infections	6.319	6.275	6.237	6.187	6.185
HCC008	Metastatic Cancer	22.979	22.560	22.379	22.335	22.336
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	13.282	12.979	12.825	12.743	12.742
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	5.575	5.376	5.248	5.144	5.141
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.845	3.648	3.517	3.409	3.405
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.604	2.457	2.350	2.254	2.251
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.132	1.017	0.903	0.779	0.775
HCC018	Pancreas Transplant Status	2.006	1.955	1.933	1.932	1.933
HCC019	Diabetes with Acute Complications	0.427	0.359	0.299	0.243	0.240
HCC020	Diabetes with Chronic Complications	0.427	0.359	0.299	0.243	0.240
HCC021	Diabetes without Complication	0.427	0.359	0.299	0.243	0.240
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19-21	0.384	0.350	0.319	0.257	0.255
HCC023	Protein-Calorie Malnutrition	10.719	10.711	10.746	10.828	10.831
HCC026	Mucopolysaccharidosis	29.195	29.017	28.940	28.930	28.931
HCC027	Lipidoses and Glycogenosis	29.195	29.017	28.940	28.930	28.931
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	7.748	7.653	7.595	7.554	7.553
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.789	1.713	1.648	1.584	1.582
HCC034	Liver Transplant Status/Complications	9.695	9.633	9.608	9.605	9.604

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC035_1*	Acute Liver Failure/Disease, Including Neonatal Hepatitis	9.532	9.480	9.468	9.490	9.489
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	3.107	2.965	2.901	2.873	2.872
HCC036	Cirrhosis of Liver	1.038	0.951	0.885	0.819	0.816
HCC037_1	Chronic Viral Hepatitis C	0.871	0.785	0.717	0.653	0.651
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.871	0.785	0.717	0.653	0.651
HCC041	Intestine Transplant Status/Complications	33.660	33.619	33.587	33.545	33.545
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	8.835	8.653	8.577	8.561	8.562
HCC045	Intestinal Obstruction	5.241	5.066	4.982	4.928	4.927
HCC046	Chronic Pancreatitis	3.546	3.407	3.355	3.341	3.342
HCC047	Acute Pancreatitis	3.034	2.855	2.755	2.665	2.664
HCC048	Inflammatory Bowel Disease	0.532	0.444	0.356	0.249	0.245
HCC054	Necrotizing Fasciitis	9.981	9.883	9.868	9.923	9.925
HCC055	Bone/Joint/Muscle Infections/Necrosis	5.231	5.080	5.019	5.016	5.016
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	1.372	1.265	1.169	1.076	1.072
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.658	0.562	0.457	0.334	0.330
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.433	2.281	2.177	2.083	2.080
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.433	2.281	2.177	2.083	2.080
HCC063	Cleft Lip/Cleft Palate	1.904	1.780	1.690	1.604	1.601
HCC066	Hemophilia	70.009	69.723	69.594	69.568	69.568
HCC067	Myelodysplastic Syndromes and Myelofibrosis	14.086	13.994	13.949	13.929	13.928
HCC068	Aplastic Anemia	14.086	13.994	13.949	13.929	13.928
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	14.086	13.994	13.949	13.929	13.928
HCC070	Sickle Cell Anemia (Hb-SS)	2.795	2.679	2.593	2.514	2.511
HCC071	Beta Thalassemia Major	2.795	2.679	2.593	2.514	2.511
HCC073	Combined and Other Severe Immunodeficiencies	4.770	4.683	4.639	4.615	4.614
HCC074	Disorders of the Immune Mechanism	4.770	4.683	4.639	4.615	4.614
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.606	2.537	2.486	2.442	2.441
HCC081	Drug Use with Psychotic Complications	2.622	2.446	2.303	2.144	2.138
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.622	2.446	2.303	2.144	2.138
HCC083	Alcohol Use with Psychotic Complications	1.224	1.095	0.995	0.891	0.887
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.224	1.095	0.995	0.891	0.887
HCC087_1	Schizophrenia	2.622	2.445	2.323	2.205	2.202
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	2.622	2.445	2.323	2.205	2.202
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	1.379	1.249	1.132	1.003	0.999

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC090	Personality Disorders	1.072	0.962	0.846	0.717	0.712
HCC094	Anorexia/Bulimia Nervosa	2.437	2.303	2.202	2.109	2.106
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	6.816	6.773	6.748	6.715	6.715
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.448	1.371	1.307	1.243	1.241
HCC102	Autistic Disorder	1.236	1.128	1.016	0.899	0.895
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	1.072	0.962	0.846	0.717	0.712
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	11.562	11.447	11.385	11.344	11.343
HCC107	Quadriplegia	11.562	11.447	11.385	11.344	11.343
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	7.825	7.689	7.610	7.549	7.547
HCC109	Paraplegia	7.825	7.689	7.610	7.549	7.547
HCC110	Spinal Cord Disorders/Injuries	5.342	5.158	5.057	4.987	4.984
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.336	3.164	3.042	2.918	2.913
HCC112	Quadriplegic Cerebral Palsy	1.238	1.070	0.963	0.872	0.870
HCC113	Cerebral Palsy, Except Quadriplegic	0.790	0.708	0.633	0.547	0.544
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.374	1.273	1.197	1.120	1.117
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.075	4.987	4.942	4.916	4.916
HCC117	Muscular Dystrophy	1.763	1.654	1.559	1.447	1.442
HCC118	Multiple Sclerosis	2.962	2.806	2.695	2.592	2.589
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	1.763	1.654	1.559	1.447	1.442
HCC120	Seizure Disorders and Convulsions	1.068	0.955	0.861	0.763	0.759
HCC121	Hydrocephalus	8.307	8.209	8.151	8.116	8.116
HCC122	Coma, Brain Compression/Anoxic Damage	7.874	7.753	7.697	7.679	7.679
HCC123	Narcolepsy and Cataplexy	5.839	5.684	5.563	5.448	5.444
HCC125	Respirator Dependence/Tracheostomy Status	21.892	21.866	21.900	21.994	21.997
HCC126	Respiratory Arrest	6.658	6.534	6.520	6.581	6.585
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	6.658	6.534	6.520	6.581	6.585
HCC128	Heart Assistive Device/Artificial Heart	26.896	26.755	26.704	26.706	26.708
HCC129	Heart Transplant Status/Complications	26.896	26.755	26.704	26.706	26.708
HCC130	Heart Failure	2.449	2.372	2.329	2.303	2.303
HCC131	Acute Myocardial Infarction	6.445	6.227	6.150	6.160	6.163
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.805	4.590	4.495	4.441	4.441
HCC135	Heart Infection/Inflammation, Except Rheumatic	5.740	5.651	5.598	5.557	5.557
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	2.586	2.489	2.409	2.341	2.338
HCC138	Major Congenital Heart/Circulatory Disorders	2.586	2.489	2.409	2.341	2.338

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	2.586	2.489	2.409	2.341	2.338
HCC142	Specified Heart Arrhythmias	2.265	2.157	2.070	1.983	1.983
HCC145	Intracranial Hemorrhage	6.694	6.498	6.395	6.327	6.327
HCC146	Ischemic or Unspecified Stroke	1.586	1.484	1.427	1.373	1.372
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.546	2.415	2.323	2.233	2.230
HCC150	Hemiplegia/Hemiparesis	4.176	4.091	4.072	4.095	4.097
HCC151	Monoplegia, Other Paralytic Syndromes	2.985	2.887	2.823	2.764	2.762
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	8.710	8.634	8.643	8.727	8.731
HCC154	Vascular Disease with Complications	6.654	6.542	6.492	6.474	6.474
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	3.510	3.396	3.316	3.234	3.232
HCC158	Lung Transplant Status/Complications	22.123	22.027	22.002	22.028	22.028
HCC159	Cystic Fibrosis	4.871	4.653	4.513	4.410	4.407
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.771	0.673	0.576	0.472	0.468
HCC161_1	Severe Asthma	0.771	0.673	0.576	0.472	0.468
HCC161_2	Asthma, Except Severe	0.771	0.673	0.576	0.472	0.468
HCC162	Fibrosis of Lung and Other Lung Disorders	1.934	1.853	1.793	1.729	1.727
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.528	6.521	6.538	6.580	6.581
HCC174	Exudative Macular Degeneration	1.570	1.440	1.327	1.197	1.193
HCC183	Kidney Transplant Status/Complications	6.027	5.868	5.765	5.671	5.673
HCC184	End Stage Renal Disease	23.533	23.284	23.237	23.356	23.397
HCC187	Chronic Kidney Disease, Stage 5	0.953	0.912	0.900	0.910	0.911
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.953	0.912	0.900	0.910	0.911
HCC203	Ectopic and Molar Pregnancy	2.088	1.879	1.688	1.430	1.421
HCC204	Miscarriage with Complications	0.848	0.732	0.579	0.375	0.365
HCC205	Miscarriage with No or Minor Complications	0.848	0.732	0.579	0.375	0.365
HCC207	Pregnancy with Delivery with Major Complications	4.049	3.741	3.498	3.132	3.123
HCC208	Pregnancy with Delivery with Complications	4.049	3.741	3.498	3.132	3.123
HCC209	Pregnancy with Delivery with No or Minor Complications	2.881	2.650	2.411	1.973	1.956
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	1.240	1.074	0.871	0.634	0.623
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.834	0.699	0.523	0.348	0.340
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.365	0.274	0.172	0.103	0.100
HCC217	Chronic Ulcer of Skin, Except Pressure	1.879	1.795	1.748	1.715	1.715
HCC218	Extensive Third Degree Burns	18.976	18.728	18.594	18.523	18.521
HCC219	Major Skin Burn or Condition	2.884	2.767	2.683	2.612	2.609
HCC223	Severe Head Injury	15.439	15.331	15.260	15.212	15.210
HCC226	Hip and Pelvic Fractures	8.537	8.317	8.230	8.224	8.225

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC228	Vertebral Fractures without Spinal Cord Injury	4.959	4.798	4.692	4.599	4.596
HCC234	Traumatic Amputations and Amputation Complications	5.447	5.311	5.259	5.255	5.256
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	25.813	25.812	25.822	25.845	25.846
HCC253	Artificial Openings for Feeding or Elimination	7.305	7.240	7.229	7.258	7.259
HCC254	Amputation Status, Upper Limb or Lower Limb	1.987	1.884	1.830	1.795	1.795
Severity Factors						
SEVERE x HCC006	Severe illness x Opportunistic Infections	6.236	6.388	6.514	6.663	6.667
SEVERE x HCC008	Severe illness x Metastatic Cancer	6.236	6.388	6.514	6.663	6.667
SEVERE x HCC009	Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	6.236	6.388	6.514	6.663	6.667
SEVERE x HCC010	Severe illness x Non-Hodgkin Lymphomas and Other Cancers and Tumors	6.236	6.388	6.514	6.663	6.667
SEVERE x HCC115	Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	6.236	6.388	6.514	6.663	6.667
SEVERE x HCC135	Severe illness x Heart Infection/Inflammation, Except Rheumatic	6.236	6.388	6.514	6.663	6.667
SEVERE x HCC145	Severe illness x Intracranial Hemorrhage	6.236	6.388	6.514	6.663	6.667
SEVERE x G06A	Severe illness x HCC group G06A (HCC 67 Myelodysplastic Syndromes and Myelofibrosis or HCC 68 Aplastic Anemia or HCC 69 Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn)	6.236	6.388	6.514	6.663	6.667
SEVERE x G08	Severe illness x HCC group G08 (HCC 73 Combined and Other Severe Immunodeficiencies or HCC 74 Disorders of the Immune Mechanism)	6.236	6.388	6.514	6.663	6.667
Enrollment Duration Factors						
	1 month of enrollment	0.275	0.226	0.207	0.188	0.188
	2 months of enrollment	0.260	0.210	0.190	0.175	0.175
	3 months of enrollment	0.277	0.224	0.199	0.184	0.183
	4 months of enrollment	0.217	0.171	0.148	0.136	0.136
	5 months of enrollment	0.203	0.162	0.139	0.127	0.127
	6 months of enrollment	0.170	0.134	0.113	0.102	0.101
	7 months of enrollment	0.128	0.101	0.084	0.074	0.074
	8 months of enrollment	0.088	0.069	0.055	0.048	0.048
	9 months of enrollment	0.049	0.036	0.027	0.021	0.021
	10 months of enrollment	0.004	0.001	0.000	0.000	0.000
	11 months of enrollment	0.001	0.000	0.000	0.000	0.000
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	8.719	8.138	7.742	7.323	7.313
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	6.743	6.306	6.111	6.038	6.042
RXC 03	Antiarrhythmics	0.113	0.103	0.100	0.067	0.049

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 04	Phosphate Binders	2.045	2.052	2.043	1.988	1.911
RXC 05	Inflammatory Bowel Disease Agents	1.805	1.670	1.528	1.322	1.314
RXC 06	Insulin	1.626	1.437	1.238	1.043	1.035
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.785	0.676	0.555	0.397	0.391
RXC 08	Multiple Sclerosis Agents	23.781	22.923	22.485	22.214	22.215
RXC 09	Immune Suppressants and Immunomodulators **	17.156	16.639	16.445	16.445	16.448
RXC 10	Cystic Fibrosis Agents	17.920	17.605	17.496	17.496	17.499
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001	2.213	2.397	2.671	3.133	3.148
RXC 02 x HCC037_1, 036, 035_2, 035 1, 34	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035 2 or 035 1 or 034)	-0.658	-0.550	-0.444	-0.312	-0.308
RXC 03 x HCC142	Additional effect for enrollees with RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC 04 x HCC184, 183, 187, 188	Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188)	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041)	-0.374	-0.313	-0.248	-0.170	-0.167
RXC 06 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021)	0.214	0.281	0.371	0.401	0.404
RXC 07 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021)	-0.427	-0.359	-0.299	-0.243	-0.240
RXC 08 x HCC118	Additional effect for enrollees with RXC 08 and HCC 118	-0.256	0.207	0.550	0.938	0.944
RXC 09 x HCC056 or 057 and 048 or 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057)	0.859	0.989	1.098	1.229	1.234
RXC 09 x HCC056	Additional effect for enrollees with RXC 09 and HCC 056	-1.372	-1.265	-1.169	-1.076	-1.072
RXC 09 x HCC057	Additional effect for enrollees with RXC 09 and HCC 057	-0.658	-0.562	-0.457	-0.334	-0.330
RXC 09 x HCC048, 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041)	-0.250	-0.202	-0.156	-0.098	-0.096
RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	47.572	47.627	47.694	47.819	47.822

* HCC numbers that appear with an underscore in this document will appear without the underscore in the DIY software. For example, HCC 35_1 in this table will appear as HCC 351 in the DIY software.

** The coefficients for RXC 09 Immune Suppressants and Immunomodulators, the HCC factors relevant for RXC 09 (HCC041, HCC048, HCC056, HCC057), and the related RXC 09 interactions (RXC 09 x HCC056 or 057 and 048 or 041; RXC 09 x HCC056; RXC 09 x HCC057; RXC 09 x HCC048, 041) result from the equally weighted (averaged) blended factors from separately solved models using only the 2016 and 2017 enrollee-level EDGE data and are otherwise consistent with the policies finalized in this rulemaking. See the preamble discussion that follows for more details.

TABLE 2: HHS HCCs in the Adult Model Severity Illness Indicator Variables

HCC No.	Factor
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
HCC120	Seizure Disorders and Convulsions
HCC122	Coma, Brain Compression/Anoxic Damage
HCC125	Respirator Dependence/Tracheostomy Status
HCC126	Respiratory Arrest
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes
HCC156	Pulmonary Embolism and Deep Vein Thrombosis

* This table contains the same list of HCCs that applied to the severity factors in the 2020 and 2021 benefit years. See, for example, Table 2 in the 2020 Payment Notice, 84 FR 17454 at 17474. The table was inadvertently not published in the final 2021 benefit year risk adjustment model coefficients document. As such, the same list of HCCs that will apply to the severity factors for the 2022 benefit year applied in the 2020 and 2021 benefit years.

TABLE 3: Child Risk Adjustment Model Factors for 2022 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2-4, Male	0.230	0.162	0.112	0.073	0.072
Age 5-9, Male	0.170	0.112	0.071	0.045	0.044
Age 10-14, Male	0.203	0.143	0.099	0.072	0.071
Age 15-20, Male	0.243	0.179	0.126	0.087	0.086
Age 2-4, Female	0.177	0.118	0.079	0.051	0.050
Age 5-9, Female	0.122	0.070	0.037	0.016	0.015
Age 10-14, Female	0.191	0.134	0.092	0.068	0.067
Age 15-20, Female	0.265	0.187	0.122	0.073	0.071
Diagnosis Factors					
HIV/AIDS	5.846	5.446	5.222	5.058	5.054
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	13.076	12.930	12.869	12.835	12.836
Central Nervous System Infections, Except Viral Meningitis	8.033	7.897	7.841	7.828	7.829
Viral or Unspecified Meningitis	2.626	2.467	2.337	2.169	2.164
Opportunistic Infections	14.919	14.904	14.887	14.864	14.863
Metastatic Cancer	35.966	35.740	35.635	35.613	35.613
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.220	8.990	8.841	8.727	8.723
Non-Hodgkin Lymphomas and Other Cancers and Tumors	7.178	6.963	6.810	6.674	6.670
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	4.342	4.197	4.079	3.955	3.950
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	4.342	4.197	4.079	3.955	3.950
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	0.924	0.809	0.700	0.579	0.575
Pancreas Transplant Status	8.841	8.686	8.586	8.485	8.483
Diabetes with Acute Complications	2.612	2.363	2.134	1.805	1.795
Diabetes with Chronic Complications	2.612	2.363	2.134	1.805	1.795
Diabetes without Complication	2.612	2.363	2.134	1.805	1.795
Protein-Calorie Malnutrition	13.566	13.485	13.464	13.485	13.486
Mucopolysaccharidosis	39.839	39.617	39.513	39.472	39.471
Lipidoses and Glycogenosis	39.839	39.617	39.513	39.472	39.471
Congenital Metabolic Disorders, Not Elsewhere Classified	5.822	5.719	5.642	5.576	5.573

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Amyloidosis, Porphyria, and Other Metabolic Disorders	5.822	5.719	5.642	5.576	5.573
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.837	6.621	6.500	6.442	6.440
Liver Transplant Status/Complications	8.841	8.686	8.586	8.485	8.483
Acute Liver Failure/Disease, Including Neonatal Hepatitis	17.574	17.546	17.579	17.664	17.668
Chronic Liver Failure/End-Stage Liver Disorders	13.757	13.669	13.631	13.602	13.601
Cirrhosis of Liver	4.121	4.067	4.026	3.972	3.974
Chronic Viral Hepatitis C	2.621	2.479	2.402	2.390	2.391
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.132	0.091	0.054	0.016	0.015
Intestine Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.679	11.439	11.329	11.294	11.295
Intestinal Obstruction	5.173	5.010	4.892	4.779	4.775
Chronic Pancreatitis	12.085	11.919	11.851	11.844	11.845
Acute Pancreatitis	7.147	6.966	6.850	6.733	6.731
Inflammatory Bowel Disease	9.151	8.799	8.595	8.441	8.437
Necrotizing Fasciitis	3.587	3.403	3.278	3.181	3.178
Bone/Joint/Muscle Infections/Necrosis	3.587	3.403	3.278	3.181	3.178
Rheumatoid Arthritis and Specified Autoimmune Disorders	5.087	4.860	4.711	4.609	4.606
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.678	0.566	0.450	0.321	0.316
Osteogenesis Imperfecta and Other Osteodystrophies	1.313	1.210	1.124	1.042	1.039
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.313	1.210	1.124	1.042	1.039
Cleft Lip/Cleft Palate	1.185	1.042	0.922	0.789	0.784
Hemophilia	71.879	71.450	71.242	71.155	71.154
Myelodysplastic Syndromes and Myelofibrosis	15.280	15.144	15.071	15.026	15.025
Aplastic Anemia	15.280	15.144	15.071	15.026	15.025
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	15.280	15.144	15.071	15.026	15.025
Sickle Cell Anemia (Hb-SS)	5.410	5.204	5.058	4.935	4.931
Beta Thalassemia Major	5.410	5.204	5.058	4.935	4.931
Combined and Other Severe Immunodeficiencies	5.839	5.714	5.636	5.578	5.576
Disorders of the Immune Mechanism	5.839	5.714	5.636	5.578	5.576
Coagulation Defects and Other Specified Hematological Disorders	4.605	4.499	4.413	4.331	4.329
Drug Use with Psychotic Complications	2.924	2.758	2.632	2.496	2.491
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.924	2.758	2.632	2.496	2.491
Alcohol Use with Psychotic Complications	1.113	0.972	0.844	0.716	0.712
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.113	0.972	0.844	0.716	0.712
Schizophrenia	4.606	4.331	4.146	3.976	3.970
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.008	2.800	2.630	2.454	2.448
Major Depressive Disorder, Severe, and Bipolar Disorders	2.668	2.474	2.307	2.135	2.128
Personality Disorders	0.452	0.356	0.244	0.126	0.121
Anorexia/Bulimia Nervosa	2.154	1.987	1.858	1.740	1.736

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	1.637	1.531	1.457	1.379	1.376
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.447	1.334	1.245	1.151	1.148
Autistic Disorder	2.668	2.474	2.307	2.135	2.128
Pervasive Developmental Disorders, Except Autistic Disorder	0.457	0.369	0.267	0.166	0.162
Traumatic Complete Lesion Cervical Spinal Cord	11.900	11.756	11.694	11.680	11.681
Quadriplegia	11.900	11.756	11.694	11.680	11.681
Traumatic Complete Lesion Dorsal Spinal Cord	8.823	8.627	8.523	8.442	8.440
Paraplegia	8.823	8.627	8.523	8.442	8.440
Spinal Cord Disorders/Injuries	3.939	3.770	3.640	3.514	3.509
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	31.125	30.906	30.769	30.671	30.669
Quadriplegic Cerebral Palsy	3.767	3.620	3.568	3.551	3.553
Cerebral Palsy, Except Quadriplegic	0.599	0.481	0.379	0.257	0.252
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	2.207	2.103	2.029	1.960	1.957
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	11.008	10.884	10.839	10.844	10.845
Muscular Dystrophy	4.534	4.387	4.277	4.164	4.161
Multiple Sclerosis	12.970	12.611	12.453	12.402	12.402
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	4.534	4.387	4.277	4.164	4.161
Seizure Disorders and Convulsions	2.113	1.977	1.844	1.705	1.699
Hydrocephalus	4.439	4.348	4.290	4.251	4.250
Coma, Brain Compression/Anoxic Damage	4.611	4.505	4.439	4.386	4.385
Narcolepsy and Cataplexy	5.128	4.967	4.827	4.671	4.664
Respirator Dependence/Tracheostomy Status	31.476	31.422	31.478	31.622	31.628
Respiratory Arrest	10.252	10.067	9.988	9.945	9.946
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	10.252	10.067	9.988	9.945	9.946
Heart Assistive Device/Artificial Heart	16.842	16.819	16.822	16.830	16.829
Heart Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829
Heart Failure	6.072	5.984	5.925	5.881	5.879
Acute Myocardial Infarction	2.568	2.506	2.484	2.472	2.473
Unstable Angina and Other Acute Ischemic Heart Disease	2.568	2.506	2.484	2.472	2.473
Heart Infection/Inflammation, Except Rheumatic	11.667	11.585	11.544	11.523	11.522
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	3.945	3.787	3.648	3.536	3.532
Major Congenital Heart/Circulatory Disorders	1.238	1.131	1.010	0.907	0.903
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.750	0.653	0.558	0.481	0.479
Specified Heart Arrhythmias	3.495	3.352	3.245	3.157	3.154
Intracranial Hemorrhage	9.192	9.061	9.001	8.970	8.969
Ischemic or Unspecified Stroke	2.749	2.696	2.677	2.666	2.667
Cerebral Aneurysm and Arteriovenous Malformation	3.235	3.082	2.980	2.885	2.881
Hemiplegia/Hemiparesis	6.650	6.551	6.492	6.441	6.439
Monoplegia, Other Paralytic Syndromes	4.100	3.979	3.898	3.817	3.813

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Atherosclerosis of the Extremities with Ulceration or Gangrene	12.487	12.317	12.221	12.151	12.150
Vascular Disease with Complications	10.670	10.600	10.582	10.602	10.604
Pulmonary Embolism and Deep Vein Thrombosis	16.697	16.623	16.602	16.606	16.607
Lung Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829
Cystic Fibrosis	48.890	48.432	48.224	48.173	48.173
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	2.923	2.793	2.682	2.564	2.561
Severe Asthma	0.807	0.642	0.473	0.284	0.277
Asthma, Except Severe	0.326	0.244	0.155	0.081	0.078
Fibrosis of Lung and Other Lung Disorders	1.481	1.388	1.299	1.221	1.218
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.551	6.508	6.495	6.508	6.509
Kidney Transplant Status/Complications	8.841	8.686	8.586	8.485	8.483
End Stage Renal Disease	41.577	41.472	41.473	41.558	41.561
Chronic Kidney Disease, Stage 5	4.600	4.492	4.394	4.283	4.279
Chronic Kidney Disease, Severe (Stage 4)	4.600	4.492	4.394	4.283	4.279
Ectopic and Molar Pregnancy	1.923	1.710	1.517	1.269	1.263
Miscarriage with Complications	0.748	0.621	0.449	0.237	0.227
Miscarriage with No or Minor Complications	0.748	0.621	0.449	0.237	0.227
Pregnancy with Delivery with Major Complications	3.475	3.173	2.908	2.463	2.447
Pregnancy with Delivery with Complications	3.475	3.173	2.908	2.463	2.447
Pregnancy with Delivery with No or Minor Complications	2.381	2.158	1.902	1.424	1.402
(Ongoing) Pregnancy without Delivery with Major Complications	0.695	0.548	0.358	0.177	0.172
(Ongoing) Pregnancy without Delivery with Complications	0.695	0.548	0.358	0.177	0.172
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.349	0.244	0.120	0.014	0.011
Chronic Ulcer of Skin, Except Pressure	2.815	2.721	2.638	2.567	2.565
Extensive Third Degree Burns	16.569	16.375	16.274	16.231	16.229
Major Skin Burn or Condition	2.060	1.921	1.808	1.694	1.690
Severe Head Injury	16.569	16.375	16.274	16.231	16.229
Hip and Pelvic Fractures	4.530	4.320	4.167	4.054	4.052
Vertebral Fractures without Spinal Cord Injury	3.934	3.751	3.603	3.446	3.440
Traumatic Amputations and Amputation Complications	4.758	4.565	4.430	4.284	4.279
Stem Cell, Including Bone Marrow, Transplant Status/Complications	16.842	16.819	16.822	16.830	16.829
Artificial Openings for Feeding or Elimination	10.291	10.196	10.202	10.268	10.272
Amputation Status, Upper Limb or Lower Limb	4.758	4.565	4.430	4.284	4.279

TABLE 4: Infant Risk Adjustment Model Factors for 2022 Benefit Year

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	219.854	218.550	217.927	217.743	217.744
Extremely Immature * Severity Level 4	142.713	141.194	140.396	140.023	140.018
Extremely Immature * Severity Level 3	32.417	31.185	30.495	30.117	30.109
Extremely Immature * Severity Level 2	32.417	31.185	30.495	30.117	30.109
Extremely Immature * Severity Level 1 (Lowest)	32.417	31.185	30.495	30.117	30.109

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Immature * Severity Level 5 (Highest)	130.150	128.727	128.031	127.783	127.781
Immature * Severity Level 4	68.882	67.469	66.748	66.449	66.443
Immature * Severity Level 3	32.417	31.185	30.495	30.117	30.109
Immature * Severity Level 2	25.400	24.244	23.568	23.149	23.138
Immature * Severity Level 1 (Lowest)	25.400	24.244	23.568	23.149	23.138
Premature/Multiples * Severity Level 5 (Highest)	107.912	106.702	106.087	105.833	105.828
Premature/Multiples * Severity Level 4	28.422	27.186	26.499	26.110	26.103
Premature/Multiples * Severity Level 3	14.035	13.101	12.435	11.838	11.817
Premature/Multiples * Severity Level 2	7.977	7.290	6.663	5.951	5.922
Premature/Multiples * Severity Level 1 (Lowest)	5.674	5.092	4.517	3.966	3.945
Term * Severity Level 5 (Highest)	81.816	80.759	80.174	79.859	79.852
Term * Severity Level 4	15.824	14.941	14.315	13.754	13.738
Term * Severity Level 3	5.991	5.423	4.855	4.253	4.230
Term * Severity Level 2	3.567	3.090	2.524	1.922	1.897
Term * Severity Level 1 (Lowest)	1.808	1.450	1.001	0.720	0.710
Age1 * Severity Level 5 (Highest)	62.403	61.770	61.417	61.239	61.234
Age1 * Severity Level 4	12.415	11.949	11.629	11.372	11.364
Age1 * Severity Level 3	3.129	2.858	2.629	2.433	2.426
Age1 * Severity Level 2	1.972	1.743	1.522	1.314	1.306
Age1 * Severity Level 1 (Lowest)	0.571	0.494	0.441	0.403	0.402
Age 0 Male	0.606	0.567	0.529	0.460	0.457
Age 1 Male	0.103	0.086	0.069	0.050	0.049

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
Severity Level 5	Liver Transplant Status/Complications
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 Status/Complications
Severity Level 5	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/Complications
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	Adrenal, Pituitary, and Other Significant Endocrine Disorders

Severity Category	HCC/Description
Severity Level 4	Acute Liver Failure/Disease, Including Neonatal Hepatitis
Severity Level 4	Chronic Liver Failure/End-Stage Liver Disorders
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	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	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 Lymphomas and Other Cancers and Tumors
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers
Severity Level 3	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors
Severity Level 3	Lipidoses and Glycogenosis
Severity Level 3	Intestinal Obstruction
Severity Level 3	Necrotizing Fasciitis
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies
Severity Level 3	Cleft Lip/Cleft Palate
Severity Level 3	Hemophilia
Severity Level 3	Disorders of the Immune Mechanism
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders
Severity Level 3	Drug Use with Psychotic Complications
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
Severity Level 3	Alcohol Use with Psychotic Complications
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
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	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
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 Category	HCC/Description
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	Extensive Third Degree Burns
Severity Level 3	Severe Head Injury
Severity Level 3	Hip and Pelvic Fractures
Severity Level 3	Vertebral Fractures without Spinal Cord Injury
Severity Level 2	Viral or Unspecified Meningitis
Severity Level 2	Thyroid Cancer, 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	Acute 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	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes
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	Severe Asthma
Severity Level 2	Fibrosis of Lung and Other Lung Disorders
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4)
Severity Level 2	Chronic Ulcer of Skin, Except Pressure
Severity Level 2	Major Skin Burn or Condition
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C
Severity Level 1	Beta 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, Except Severe
Severity Level 1	Traumatic Amputations and Amputation Complications
Severity Level 1	Amputation Status, Upper Limb or Lower Limb

We received public comments on the proposed list of factors to be employed in the 2022 benefit year risk adjustment models (§ 153.320). The following is a summary of the comments on these proposals and our responses.

Comment: A few commenters expressed concerns that the HCC coefficients in the list of factors would adversely affect individuals with preexisting conditions or diagnosed disabilities. One of these commenters was also concerned with the gender differences in the list of factors.

Response: The list of factors for the adult, child, and infant risk adjustment models include the coefficients in the statistical models developed by HHS to predict the plan liability for an average enrollee based on demographics, diagnosed conditions (grouped into HCCs), enrollment duration (for the adult models), and prescription drugs (for the adult models). The list of factors represents the different levels of risk plans take on in providing health coverage to enrollees. These factors do not affect enrollee costs and therefore do not adversely affect any consumers, including individuals with preexisting conditions or diagnosed disabilities or based on gender. Rather, the purpose of the risk adjustment program is to transfer funds from risk adjustment covered plans with lower than average risk to risk adjustment covered plans with higher than average risk, with the goal of minimizing adverse selection and providing coverage to all consumers. Therefore, these factors actually help individuals with preexisting conditions or diagnosed disabilities through compensating plans more for more severe conditions, incentivizing plans to cover such individuals rather than avoid covering them. In addition, gender differences in the list of factors that will be used for the HHS risk adjustment models do not result in differences in premium paid by male and female enrollees.⁶⁸ Rather, the different age-sex factors represent differences in the level of risk plans take on in providing coverage to men and women; for example, adult women within childbearing years tend to cost more than men of the same age due to pregnancy and childbirth.

Comment: A few commenters made suggestions for additions to or deletions from the list of factors. These commenters asked that HHS not include acute, unpredictable HCCs in the list of factors, such as the severe head injury and extensive third degree burns HCCs, as these conditions do not differentiate adverse selection risk. One of these commenters asked that HHS bifurcate transplant status codes into a set of coefficients for transplant procedure codes and

⁶⁸ Section 2701 of the PHS Act prohibits issuers of non-grandfathered coverage in the individual and small group markets from varying rates with respect to any characteristic aside from whether the plan covers an individual or a family, rating area, age, and tobacco use. Therefore, those four factors held constant, female enrollees cannot be charged higher premiums than male enrollees, and vice versa, for the same plan.

another set of coefficients for transplant history or status. Another commenter suggested that HHS simplify the risk adjustment models by combining coefficients for HCCs where similar risk selection patterns would result in minimal member-level prediction improvements when risk scores are averaged at the plan level to calculate the plan liability risk score.

Response: We continue to believe that the acute conditions identified by these commenters (severe head injury and extensive third degree burns) should be included in the risk adjustment models. We detailed our consideration of incorporating these HCCs in the risk adjustment models in the paper on the Potential Updates to HHS-HCCs for the HHS-operated Risk Adjustment Program.⁶⁹ For example, we explained that severe head injury represents a condition with ongoing care costs, similar to other injury HCCs currently included in the V05 models⁷⁰ (for example, hip fractures and vertebral fractures). Stakeholders also had an opportunity to comment on the addition of these HCCs as part of the 2021 Payment Notice rulemaking.⁷¹ Based on our analysis, these conditions indicate the presence of underlying chronic conditions and frailty, were underpredicted in the risk adjustment models, and have high costs in the year after the diagnosis.⁷² Therefore, we do not agree that the HCCs for severe head injury and extensive third degree burns do not differentiate adverse selection risk, and we believe they are appropriate to include in the risk adjustment models, as previously stated in the 2021 Payment Notice final rule.⁷³ There is evidence of ongoing chronic costs associated with these conditions, and issuers can potentially adversely select against enrollees with a higher risk of incurring costs related to these conditions in a given benefit year. Isolating and omitting the near-term ongoing costs for these conditions would reduce the predictive accuracy of the model without any benefit in reduced model complexity, as the costs for the excluded near-term codes

⁶⁹ Potential Updates to HHS-HCCs for the HHS-operated Risk Adjustment Program. June 17, 2019. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf>.

⁷⁰ The shorthand “V05” refers to the HHS–HCC classification for the HHS risk adjustment models that applies through the 2020 benefit year.

⁷¹ 85 FR 7088 at 7098 through 7101. Also see 85 FR 29164 at 29181.

⁷² 85 FR 29164 at 29181.

⁷³ 85 FR 29164 at 29181.

would end up in the associated longer term HCCs. The ability to separate costs associated with the acute event and chronic conditions can be complex for certain HCCs, including severe head injury, extensive third degree burns, and transplants. We also believe that by including the acute costs for these conditions, we are also accounting for the ongoing costs of care during the first year. The continued inclusion of these HCCs in the risk adjustment models, as proposed, is consistent with our goals to improve model prediction and identify chronic or systematic conditions that represent insurance risk selection or risk segmentation. In addition, both of these HCCs – extensive third degree burns and severe head injury – are also payment HCCs in Medicare’s CMS-HCC models. As for transplant procedure versus transplant status, we do not currently use procedure codes to define any HCCs, but we are interested in analyzing this topic for further consideration for potential model changes in future benefit years.

Consistent with the risk adjustment principles described previously,⁷⁴ the HHS-operated risk adjustment models exclude HCCs containing diagnoses that are vague or nonspecific (for example, cough), discretionary in medical treatment or coding (for example, attention deficit disorder), or not medically significant (for example, heartburn). The payment models also exclude HCCs that do not add empirically to costs (for example, non-melanoma forms of skin cancer). We did not propose to combine HCCs and are not finalizing combining HCCs in the 2022 risk adjustment models. At this time, we do not believe that combining HCCs for reasons stated by the commenter is necessary, as we have already analyzed and selected HCCs for inclusion in the models that capture the largest risk differences. However, in our efforts to continuously improve the risk adjustment models, we will continue to analyze the risk adjustment model factors for future benefit years and consider whether changes are needed.

⁷⁴ See, for example, the 2021 Payment Notice, and Section 2.1 of the “March 31, 2016 HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper,” March 24, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

For all these reasons, we believe the proposed and final list of factors applicable to the 2022 benefit year includes the appropriate HCCs.

Comment: One commenter suggested creating separate models for the individual and small group markets, using only individual market enrollee-level EDGE data for the individual market models but supplementing small group market enrollee-level EDGE data with MarketScan® data for the small group market models.

Response: We did not propose and are not finalizing separate individual and small group market models. At this time, we are concerned that creating two separate risk adjustment models for the individual and small group markets for each of the age groups (adult, child, and infant) would result in significantly increased complexity of the risk adjustment program. For example, this would double the number of risk adjustment models, complicating rate setting for issuers and destabilizing the child and infant models due to small sample sizes. However, we intend to continue to analyze the differences in costs and utilization between the individual and small group markets to consider whether these types of changes would be necessary or appropriate in future benefit years. A more detailed discussion of our current analysis of these issues based on our review of the 2016, 2017 and 2018 enrollee-level EDGE data appears in the proposed rule as part of the discussion of the proposed changes to the adult model enrollment duration factors.⁷⁵

After consideration of comments on the proposed factors, we are finalizing the above list of final coefficients for the 2022 benefit year.

As noted above in the Pricing Adjustment for the Hepatitis C Drugs preamble, we continuously assess the availability of drugs in the market and the associated mapping of those drugs to RXCs in the adult risk adjustment models. As a result of this ongoing assessment, we make quarterly updates to the RXC Crosswalk to ensure drugs are being mapped to RXCs where appropriate, including adding and removing new and old drugs based on approval status, prescribing patterns, and expenditure data. In a recent update, HHS removed

⁷⁵ See 85 FR at 78585.

hydroxychloroquine from RXC 09 effective March 24, 2021, due to concerns regarding unrepresentative expenditures and off-label prescribing during the COVID-19 public health emergency.⁷⁶ Additionally, based on pre-2020 data, HHS’s analysis showed that the costs of hydroxychloroquine are much lower than the costs of other drugs that one with HCC 048, 056, or 057 may take. However, hydroxychloroquine still appears in the 2018 enrollee-level EDGE data we are otherwise finalizing for use for 2022 benefit year model recalibration. Therefore, we only used 2016 and 2017 enrollee-level EDGE data for the limited purpose of developing the RXC 09 coefficients, RXC 09 HCC related coefficients, and RXC 09 interaction term coefficients for the 2022 benefit year adult models.⁷⁷ This approach best aligns the 2022 benefit year adult model coefficients with the removal of hydroxychloroquine from RXC 09 and avoids the undesired impact of diluting the coefficient values for RXC 09 (including the associated interactions). As seen in Table 1, the coefficients for RXC 09 Immune Suppressants and Immunomodulators, the HCC factors relevant for RXC 09 (HCC41, HCC48, HCC56, HCC57), and the related RXC 09 interactions (RXC 09 x HCC056 or 057 and 048 or 041; RXC 09 x HCC056; RXC 09 x HCC057; RXC 09 x HCC048, 041) result from the equally weighted (averaged) blended factors from separately solved models using only the 2016 and 2017 enrollee-level EDGE data.

f. Cost-Sharing Reduction Adjustments

We proposed to continue including an adjustment for the receipt of 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 2022 benefit year, to maintain stability and certainty for issuers, we proposed to maintain the CSR factors finalized in the 2019, 2020, and 2021 Payment Notices.⁷⁸

⁷⁶ See HHS-Developed Risk Adjustment Model Algorithm “Do It Yourself (DIY)” Software Instructions for the 2020 Benefit Year, April 15, 2021 Update, available at <https://www.cms.gov/files/document/cy2020-diy-instructions04132021.pdf>.

⁷⁷ The same concern was not present for the 2016 and 2017 enrollee-level EDGE data because hydroxychloroquine was not included in the crosswalk until 2018.

⁷⁸ See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; and 85 FR 29164 at 29190.

Consistent with the approach finalized in the 2017 Payment Notice,⁷⁹ we also proposed to continue to use a CSR adjustment factor 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 AVs above 94 percent.

We are finalizing the CSR adjustment factors as proposed, including the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans.

We received public comments on the proposed cost-sharing reduction adjustments. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed CSR adjustment factors for the 2022 benefit year and continuing the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans. Some of these commenters stated that the current CSR adjustment factors will ensure stability and that the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans appropriately accounts for the different market dynamics and the level of wrapped benefits in Massachusetts.

Response: We are finalizing the CSR adjustment factors as proposed. Consistent with the approach finalized in the 2017 Payment Notice,⁸⁰ we will continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation for the 2022 benefit year, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent. We agree that the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans accounts for the state's unique market dynamics, and that the continuation of the current CSR adjustment factors for all states and the District of Columbia lend stability to the markets.

Comment: Some commenters wanted HHS to analyze the CSR adjustment factors for future benefit years to consider whether changes are needed. These commenters specifically

⁷⁹ See 81 FR 12203 at 12228.

⁸⁰ Ibid.

asked HHS to consider factors like whether or not the state expanded Medicaid or offers a Basic Health Program, as well as the impact of the discontinuation of CSR payments and implementation of silver loading, in analyzing the CSR adjustment factors for future benefit years. One commenter opposed the CSR adjustment factors and stated that, as a result of these factors, the risk adjustment models overcompensate issuers for those enrolled in silver plans and undercompensate issuers for other metal level enrollees.

Response: We will continue to examine whether changes to the CSR adjustment factors are warranted in the future as more enrollee-level EDGE data becomes available. We appreciate the suggestions for analysis from commenters and may consider these and other elements in our future analysis. We note that the current CSR adjustment factors are set at a national level and do not vary by state, while the suggested analysis on the effect of expanded Medicaid or presence of a Basic Health Program would vary by state. Adopting an approach that would require further variation by state would introduce a level of complexity to the risk adjustment program, which is another factor we would consider as part of any such analysis.

Furthermore, notwithstanding the cessation of federal CSR payments to issuers in October 2017, section 1402 of the ACA requires Exchange plans to provide CSRs for eligible enrollees, and plans face increased liability for silver plan enrollees receiving CSRs. As such, the CSR adjustment factors account for the higher plan liability of CSR plans, which is not experienced by other metal level plans. Therefore, we do not believe that the presence of CSR multipliers for CSR-eligible enrollees in silver plans automatically creates inaccurate risk differentials between CSR eligible and non-CSR eligible enrollees. Regardless, any refinements to the HHS-operated risk adjustment methodology, including any potential changes to the CSR adjustment factors for future benefit years, would be proposed through notice-and-comment rulemaking.

After consideration of the comments received, we are finalizing the CSR adjustment factors as proposed.

TABLE 7: Cost-Sharing Reduction Adjustment

Household Income	Plan AV	Induced Utilization Factor
Silver Plan Variant Recipients		
100-150% of Federal Poverty Line (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

g. **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 ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratios are in the range of published estimates for concurrent risk adjustment models.⁸¹ The final R-squared statistic for each model that is shown in Table 8 reflects the results from each dataset used. Because we are finalizing the 2022 benefit year coefficients from separately solved models based on blended data from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data, we are publishing the R-squared statistic for each model separately to verify their statistical validity.

⁸¹ Hileman, Geof and Spenser Steele. "Accuracy of Claims-Based Risk Scoring Models." Society of Actuaries. October 2016.

The R-squared statistic for each model is shown in Table 8.

TABLE 8: R-Squared Statistic for Proposed HHS Risk Adjustment Models

Models	R-Squared Statistic		
	2016 Enrollee-level EDGE Data	2017 Enrollee-level EDGE Data	2018 Enrollee-level EDGE Data
Platinum Adult	0.4401	0.4371	0.4232
Gold Adult	0.4349	0.4314	0.4174
Silver Adult	0.4314	0.4276	0.4134
Bronze Adult	0.4281	0.4241	0.4096
Catastrophic Adult	0.4279	0.4239	0.4094
Platinum Child	0.3147	0.3330	0.3366
Gold Child	0.3108	0.3291	0.3327
Silver Child	0.3076	0.3259	0.3295
Bronze Child	0.3041	0.3225	0.3261
Catastrophic Child	0.3040	0.3224	0.3259
Platinum Infant	0.3276	0.3289	0.3095
Gold Infant	0.3244	0.3255	0.3061
Silver Infant	0.3224	0.3234	0.3039
Bronze Infant	0.3206	0.3215	0.3020
Catastrophic Infant	0.3205	0.3215	0.3020

We received comments on the model performance statistics outlined in the proposed rule.

The following is a summary of the comments we received and our responses.

Comment: One commenter requested more information on blending the coefficients from separately solved models based on the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data and publishing the R-squared statistic for each model separately to verify their statistical validity.

Response: 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 2022 benefit year, namely the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data.⁸² As stated in the proposed rule and the preamble section above, because we blended the coefficients from separately solved models based on these 3 years of enrollee-level EDGE data that were available at the time of the proposed rule, we publish the R-squared statistic for each model separately to verify their statistical validity.

⁸² Our approach to recalibration involves using blended, or averaged, coefficients from three years of separately solved models, which promotes stability for the risk adjustment coefficients year over year, particularly for conditions with small sample sizes. For more details, see "March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper," March 24, 2016, available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

After consideration of the comments received on the model performance statistics and for the reasons stated in our responses, we are publishing the final R-squared statistic for each model above in Table 8.

h. Calculation of Plan Average Premium and State Average Premium Requirements for Extending Future Premium Credits (§ 153.320)

On August 4, 2020, HHS adopted temporary policies of relaxed enforcement for the premium rules set forth at 45 CFR 147.102, 155.200(f)(4), 155.400(e) and (g), 155.706(b)(6)(1)(A), 156.80(d), 156.210(a), and 156.286(a)(2) through (4) to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage.⁸³ HHS provided this flexibility with the intent of supporting continuity of coverage for individuals, families, and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE.

In prior rulemaking,⁸⁴ HHS finalized the calculation of plan average premium in the risk adjustment state payment transfer formula as equal to the actual premiums charged to plan enrollees, weighted by the number of months enrolled, and finalized the calculation of the state average premium as equal to the average of individual plan average premiums, weighted by each plan's share of statewide enrollment in the risk pool market, based on billable member months. In the interim final rule on COVID-19, HHS set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year. In the proposed rule, we proposed how HHS would treat temporary premium credits provided for purposes of applying the state payment transfer formula for the 2021 benefit year and beyond should HHS adopt a similar relaxed enforcement stance and permit such temporary premium credits in future benefit

⁸³ "Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency," August 4, 2020, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

⁸⁴ 2014 Payment Notice final rule, 78 FR 15409. Also see the 2020 Payment Notice final rule, 84 FR 17454.

years during a PHE declared by the Secretary of HHS (declared PHE).⁸⁵ For states where issuers of risk adjustment covered plans provide temporary premium credits during a declared PHE when permitted by HHS, the plan average premium and statewide average premium used in the state payment transfer formula would be calculated using issuers' adjusted premium amounts. Thus, the actual premiums billed to plan enrollees would be the amounts used in the calculations under the state payment transfer formula. This is consistent with the general approach adopted in the interim final rule on COVID-19 for temporary premium credits in the 2020 benefit year.

We further proposed that HHS would use adjusted plan premiums for all enrollees to whom the issuer has actually provided premium credits as a reduction to the applicable benefit year premiums, when calculating transfers under the state payment transfer formula for the 2021 benefit year and beyond. This approach would also extend to the calculation of transfers under the state payment transfer formula in states that receive approval for a request to reduce transfers under § 153.320(d) – that is, the lower actual premiums for which plan enrollees would be responsible would be the amounts used in the calculations under the state payment transfer formula to reflect these temporary premium credits. As such, if an issuer in a state with an approved 50 percent small group market reduction request for a given benefit year chooses to provide temporary premium credits, the state average premium will decrease, and HHS would apply the 50 percent transfer reduction to the lower PMPM payment or charge transfer amount calculated under the state payment transfer formula for that state's small group market for that benefit year. As detailed further later in this preamble, we also proposed that issuers providing these temporary premium credits must report the lower, actual premium amounts billed to plan enrollees to their respective EDGE servers. We explained that we believe that the applicable definitions of plan average premium and state average premium retain the meaning previously finalized by reflecting the actual monthly premium billed to enrollees. The proposal would build

⁸⁵ The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: (a) a disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

on lessons learned from the COVID-19 PHE and would establish a framework to recognize premium credits as a reduction in premium for purposes of the HHS-operated risk adjustment program to align risk adjustment charges and payments under the state payment transfer formula with flexibilities HHS may provide to issuers and states in future benefit years during a declared PHE. The proposal would not change any other aspect of the state payment transfer formula or the method for calculating payments and charges under the HHS risk adjustment methodology (inclusive of the state payment transfer formula and high-cost risk pool parameters). We are finalizing this policy as proposed.

We summarize and address all the comments received on this proposal in the Risk Adjustment Data Requirements for Future Premium Credits (§ 153.710) preamble section below.

2. Overview of the HHS Risk Adjustment Methodology (§ 153.320)

We proposed to continue to use the HHS state payment transfer formula that was finalized in the 2021 Payment Notice.⁸⁶ Although the proposed HHS state payment transfer formula for the 2022 benefit year was unchanged from what was finalized for the previous benefit year, we republished it in the proposed rule. Additionally, we republished the description of the administrative cost reduction to the statewide average premium and high-cost risk pool factors, although this reduction and the factors and terms also remain unchanged from what was finalized for the previous benefit year.⁸⁷ We also proposed to apply this state payment transfer formula, including the administrative cost reduction, for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. Under this proposal, we would no longer republish these formulas in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed. To align with this proposal, we proposed to update § 153.320(c) to replace the current language that refers to HHS specifying the applicable federally-certified risk adjustment methodology in the annual HHS notice of benefit and payment

⁸⁶ 84 FR 17454 at 17480 and 17485; and 85 FR 29164 at 29191.

⁸⁷ Ibid.

parameters for the applicable year, to instead require HHS to specify the applicable federally-certified risk adjustment methodology in notice-and-comment rulemaking that is published in advance of the applicable benefit year. We are finalizing these policies as proposed and will apply the proposed HHS risk adjustment methodology outlined in the proposed rule for the 2022 benefit year and beyond. The published methodology will remain in effect unless it is changed through future notice-and-comment rulemaking. We are also finalizing the update to § 153.320(c) as proposed.

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule.⁸⁸ In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.⁸⁹ This 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 via a cost scaling factor. In the absence of additional funding, we established, through notice-and-comment rulemaking,⁹⁰ 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. In light of the budget-neutral framework, HHS uses statewide average premium as the cost-scaling factor in the state payment transfer formula in the HHS-operated risk adjustment methodology, rather than a different

⁸⁸ 77 FR 17220 at 17246.

⁸⁹ The state payment transfer formula refers to the part of the HHS risk adjustment methodology that calculates payments and charges at the state market risk pool level prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year.

⁹⁰ 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; and 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).

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.⁹¹

Risk adjustment transfers (total payments and charges, including high-cost risk pool payments and charges) are calculated after issuers have completed their risk adjustment EDGE data submissions for the applicable benefit year. Transfers (payments and charges) under the state payment transfer formula are 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 methodology follows the formula:

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

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 denominators are 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 would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible

⁹¹ See the 2020 Payment Notice final rule for further details on why statewide average premium is the cost-scaling factor in the state payment transfer formula. See 84 FR 17454 at 17480 through 17484.

that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as measured through the combination of metal level AV, allowable rating factor, induced demand factor, and geographic cost factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers under the state payment transfer formula are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment state payment transfer calculations.⁹² This resulting PMPM plan payment or charge is multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the state. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

We previously defined the cost scaling factor, or the statewide average premium term, as the sum of the average premium per member month of each plan i (P_i) multiplied by plan i 's share of statewide enrollment in the market risk pool (s_i). We also previously adopted a 14 percent administrative cost reduction to the statewide average premium⁹³ and proposed maintaining it for the 2022 benefit year and beyond, unless amended through notice-and-comment rulemaking. The following formula shows the calculation of the statewide average premium and the adjustment to remove a portion of the administrative costs that do not vary with claims (14 percent):

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

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 .

To account for costs associated with exceptionally high-risk enrollees, we previously added a high-cost risk pool adjustment to the HHS risk adjustment methodology. As finalized in

⁹² As detailed elsewhere in this final rule, catastrophic plans are considered part of the individual market for purposes of the national high-cost risk pool payment and charge calculations.

⁹³ See 84 FR 17454 at 17486.

the 2020 Payment Notice,⁹⁴ we intend to maintain the high-cost risk pool parameters with a threshold of \$1 million and a coinsurance rate of 60 percent for benefit years 2020 and onward, unless amended through notice-and-comment rulemaking. We did not propose any changes to the high-cost risk pool parameters as part of the proposed rule; therefore, we would maintain the threshold of \$1 million and coinsurance rate of 60 percent for the 2022 benefit year.

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

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

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 ; and

⁹⁴ 84 FR 17466 through 17468.

TP_i = Plan i 's total premium amounts.

We sought comment on the proposed HHS risk adjustment methodology for the 2022 benefit year and beyond and the proposed updates to § 153.320(c). We are finalizing these policies as proposed and will apply the proposed HHS risk adjustment methodology outlined in the proposed rule for the 2022 benefit year and beyond. We are also finalizing the update to § 153.320(c) as proposed.

We received public comments on the proposed 2022 benefit year HHS risk adjustment methodology, the proposal to apply the same methodology to future benefit years unless changed through notice-and-comment rulemaking, and the proposed updates to § 153.320(c). The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed HHS risk adjustment methodology. One commenter asked HHS to continue to publish the methodology in the annual Payment Notice to prevent issuers from having to reference previous rulemakings.

Response: We appreciate the support for the state payment transfer formula and believe that maintaining the HHS risk adjustment methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking, will result in stability in the markets by making it easier for issuers to set rates because of the predictability and consistency of the methodology. We do not believe it is necessary to continue to publish the methodology in the annual Payment Notice, as we will cite to the version of the Payment Notice where the current methodology appears in subsequent Payment Notices. We are therefore finalizing the HHS risk adjustment methodology and this policy as proposed. As a result, for the 2023 benefit year and beyond, we will not republish the HHS risk adjustment methodology in the annual Payment Notice, unless we are proposing to make changes to the methodology. We are also finalizing the proposed update to § 153.320(c) to reflect this approach.

Comment: A few commenters opposed certain aspects of the state payment transfer formula, such as the use of the statewide average premium and the 14 percent administrative cost

reduction. One commenter suggested that HHS use statewide average claims rather than statewide average premium as the scaling factor in the state payment transfer formula, and further suggested that if HHS continues to use statewide average premium, HHS should increase the administrative cost reduction to 20 percent. A few commenters wanted HHS to reevaluate the state payment transfer formula, suggesting a focus on the level of the administrative cost reduction and an inquiry into whether the administrative cost reduction and the induced utilization factors should differ between the individual and small group markets. One commenter asked for more information on the administrative cost reduction, specifically what information HHS would find helpful in evaluating the sufficiency of the existing administrative cost reduction.

Response: We did not propose and are not finalizing changes to the use of the statewide average premium in the state payment transfer formula. As detailed in prior rulemakings,⁹⁵ in light of the program's budget neutral framework, HHS chose to use statewide average premium to convert required revenue and allowable premium state average factors in the state payment transfer formula from relative factors to dollar amounts so that the total calculated payment amounts equal total calculated charges in each state market risk pool. Thus, each plan in the state market risk pool receives a risk adjustment state transfer payment or charge that is scaled based on the determination of plan average risk within a state market risk pool, resulting in balanced, budget-neutral transfers. This approach supports the overall goal of the risk adjustment program to encourage issuers to rate for average risk and mitigates incentives for issuers to operate less efficiently, or to develop benefit designs or create marketing strategies to avoid high-risk enrollees. In addition, our analysis shows that statewide average claims is a volatile measure, both across states within a year and across years within a state, and would be sensitive to

⁹⁵ See, for example, the Adoption of the Methodology for the HHS-operated Risk Adjustment Program under the Patient Protection and Affordable Care Act for the 2017 Benefit Year; Final Rule, 83 FR 36456 (July 31, 2018); and the Adoption of the Methodology for the HHS-operated Risk Adjustment Program for the 2018 Benefit Year; Final Rule, 83 FR 63419 (December 10, 2018).

unexpected claims experience. Furthermore, unexpected claims experience could particularly cause instability for smaller issuers, thereby reducing the predictability of risk adjustment transfers. For these reasons, we are not proposing or otherwise considering the use of statewide average claims in the state payment transfer formula.

We also did not propose and are not finalizing changes to the 14 percent administrative cost reduction in the risk adjustment state payment transfer formula. As we noted in the 2018 Payment Notice,⁹⁶ we analyzed administrative and other non-claims expenses, including quality improvement expenses, in the MLR Annual Reporting Form, and estimated, by category, the extent to which administrative expenses varied with claims.⁹⁷ We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, to ensure that the estimated administrative cost percentage was not distorted by under- or over-pricing during the years for which MLR data were available. Using this methodology, we determined the mean administrative expense in both the individual and small group markets was 14 percent. For the 2022 benefit year, we engaged in the same analysis and arrived at the same conclusion. We set the administrative cost adjustment based on our estimate of the percentage of total costs that did not vary by risk, so that issuers with higher risk enrollees would still receive credit through risk adjustment for the cost of administrative activities that varied based on the risk of the population (for examples, discharge planning or preventing facility-acquired infections and reducing clinical errors). At this time, we have not found evidence that demonstrates that a higher percentage is necessary.

In response to comments, we further clarify that the MLR Annual Reporting Form provides all the information we use to analyze the sufficiency of the 14 percent administrative cost reduction, including administrative and other non-claims expenses like quality improvement

⁹⁶ 81 FR 94099 through 94100.

⁹⁷ In 2016 and 2017, we removed the impact of the reconciled amount of CSRs on claims costs as part of this calculation. Payments through the CSR program were discontinued in October 2017 due to lack of a Congressional appropriation. As such, although this line item still exists in the MLR Annual Reporting Form, the amount entered by issuers for the CSR line item should be zero dollars, and it therefore should no longer impact the administrative cost reduction calculation.

activity expenses, and taxes and fees that do not vary based on enrollee health risk. We believe that this is a sufficient and reasonable source for data to calculate and analyze the administrative cost reduction to the statewide average premium in the risk adjustment state payment transfer formula.

Furthermore, we did not propose and are not finalizing induced utilization factors that vary by market. We are concerned that adding different utilization factors based on market to the state payment transfer formula would make the formula much more complex, as this would double the number of induced utilization factors in the formula and make it more difficult for issuers to price for. We note that we intend to further consider the differences between markets and implications for risk adjustment, and that any related changes to the risk adjustment program would be proposed in notice-and-comment rulemaking.

Comment: One commenter asked HHS to study the correlation between risk adjustment transfers and MLR rebates, stating that it appears that transfers are too high because a number of issuers receiving risk adjustment payments must pay MLR rebates to their enrollees.

Response: While risk adjustment payments reduce the numerator of the MLR calculation,⁹⁸ whether an issuer will owe MLR rebates is influenced by a number of factors that are unrelated to risk adjustment transfers. For example, an issuer's MLR and rebate position is heavily influenced by the degree to which its pricing assumptions accurately accounted for realized claims costs for the applicable benefit year. As such, issuers may owe MLR rebates to consumers while either receiving risk adjustment payments or owing risk adjustment charges for the applicable benefit year. Additionally, our examination of the HHS risk adjustment methodology and risk adjustment data for recent benefit years has shown the program mitigates

⁹⁸ See 45 CFR 158.130(b)(5)

the influence of risk selection on premiums and the incentive for plans to avoid sicker enrollees.⁹⁹

Comment: One commenter asked that HHS reevaluate the state payment transfer formula and stated that it favors larger issuers over smaller issuers because larger issuers have the ability to dedicate resources to enable more robust coding practices.

Response: We disagree that the state payment transfer formula favors larger issuers over small issuers. The risk adjustment program transfers funds from plans with lower-than-average risk enrollees to plans with higher-than-average risk enrollees in accordance with section 1343 of the ACA, and our internal analysis has found that smaller plans that enroll sicker than average enrollees have also received high payments as a percent of their premiums. Further, HHS conducts HHS-RADV in any state where HHS operates the risk adjustment program to validate the accuracy of the data submitted by issuers to their EDGE servers.¹⁰⁰ EDGE server data are used to calculate issuers' plan liability risk scores for use in the state payment transfer formula as a part of the risk adjustment program. HHS-RADV establishes uniform audit standards to ensure that actuarial risk is accurately and consistently measured, thereby strengthening the integrity of the risk adjustment program.¹⁰¹ Therefore, any potential coding differences between plans of any size should not inappropriately impact risk adjustment, and to the extent there is any impact, it should be significantly mitigated through HHS-RADV.

Comment: One commenter requested that HHS adjust the state payment transfer formula applicable in states where HHS operates the program to ensure that charges for enrollees with no HCCs do not exceed premium.

⁹⁹ See, for example, the Summary Report on Permanent Risk Adjustment Transfers for the 2019 Benefit Year (July 17, 2020), available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/RA-Report-BY2019.pdf>; the Summary Report on Permanent Risk Adjustment Transfers for the 2018 Benefit Year (June 28, 2019), available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/Summary-Report-Risk-Adjustment-2018.pdf>; and the Summary Report on Permanent Risk Adjustment Transfers for the 2017 Benefit Year (July 9, 2018), available at <https://downloads.cms.gov/cciio/Summary-Report-Risk-Adjustment-2017.pdf>.

¹⁰⁰ See 45 CFR 153.350 and 153.630.

¹⁰¹ See, for example, the 2014 Payment Notice final rule, 78 FR 15409 at 15436 – 15438; and the 2018 Benefit Year Protocols ACA HHS Risk Adjustment Data Validation, released June 24, 2019, available at https://www.regtap.info/uploads/library/HRADV_2018Protocols_070319_5CR_070519.pdf.

Response: We do not believe that adjusting the state payment transfer formula to cap or otherwise limit charges to the level of premiums for enrollees is appropriate. We are concerned that, given the budget-neutral nature of the HHS program, a cap on charges would result in lower payments to issuers with plans with higher-than-average actuarial risk.¹⁰² The cap may also incentivize small issuers with plans that attract healthier-than-average enrollees to underprice premiums because they would know their charges would be capped to a percentage of premium. Furthermore, consistent with the framework set forth in section 1343 of the ACA, the HHS-operated risk adjustment program focuses on risk differentials at the plan level, not the enrollee level.¹⁰³ Risk adjustment transfers under the state payment transfer formula are therefore calculated based on the plan liability risk score and the statewide average premium, not based on individual enrollees' premiums. As described in a previous section of this rulemaking, we continue to consider future policy options to improve the predictive power of the risk adjustment models for certain subpopulations (including enrollees with no HCCs).

After consideration of the comments received on these proposals, we are finalizing the proposed HHS risk adjustment methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. We are also finalizing the accompanying proposed update to § 153.320(c).

3. 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 state transfers calculated by HHS under the state payment transfer formula, which is calibrated on a national dataset, for the state's individual

¹⁰² Congress did not authorize or appropriate additional funding for risk adjustment beyond the amount of charges paid in, and did not authorize HHS to obligate itself for risk adjustment payments in excess of charges collected. In the absence of additional, independent funding or the creation of budget authority in advance of an appropriation, the introduction of a cap on charges would mean that payments would have to be reduced by a similar amount because HHS cannot make payments in excess of charges collected consistent with binding appropriations law. See *New Mexico Health Connections v. United States Department of Health and Human Services*, 946 F.3d 1138 (10th Cir. 2019).

¹⁰³ Compare 42 USC 18063 (establishing the permanent risk adjustment program, which involves an assessment and comparison of the actuarial risk in each issuer's plans in a state market risk pool with the average actuarial risk of all plans in the applicable state market risk pool) with 42 USC 18061 (establishing the transitional reinsurance program, which involves an assessment of actuarial risk of individual enrollees to identify those that qualify as "high risk.")

(catastrophic or non-catastrophic risk pools), small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's markets.¹⁰⁴ We proposed that any requests received would be published in the applicable benefit year's proposed HHS notice of benefit and payment parameters, and the supporting evidence provided by the state in support of its request would be made available for public comment.¹⁰⁵

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 only make available on the CMS website 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.¹⁰⁶ 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 state payment transfer amount (T_i in the state payment transfer formula above). For the 2020 and 2021 benefit years, the state of Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market and HHS approved both requests.¹⁰⁷

We received several general comments on the state flexibility request framework outlined in § 153.320(d). However, we did not propose any changes to that framework other than the proposal to allow multi-year state flexibility requests as explained below. As such, these general comments on the state flexibility request framework are out of scope of this rulemaking and will not be addressed in this rule.

¹⁰⁴ 83 FR 16955 through 16960.

¹⁰⁵ 45 CFR 153.320(d)(3).

¹⁰⁶ See 45 CFR 153.320(d)(3).

¹⁰⁷ See 84 FR 17484 through 17485 and 85 FR 29193 through 29194.

a. Requests to Reduce Risk Adjustment Transfers for the 2022 Benefit Year

For the 2022 benefit year, HHS received a request to reduce risk adjustment transfers calculated under the state payment transfer formula for the Alabama individual¹⁰⁸ and small group markets by 50 percent.¹⁰⁹ Alabama's request states that the presence of a dominant carrier in the individual and small group markets 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 individual and small group markets for the 2022 benefit year would not exceed 1 percent, the *de minimis* premium increase threshold set forth in § 153.320(d)(1)(iii) and (d)(4)(i)(B). We sought comment on this request to reduce risk adjustment state transfers in the Alabama individual and small group markets by 50 percent for the 2022 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>. We are approving Alabama's requested reductions to 2022 benefit year transfers calculated under the state payment transfer formula for its individual and small group markets.

We received public comments on Alabama's requests to reduce risk adjustment transfers for the 2022 benefit year. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters supported Alabama's request to reduce risk adjustment transfers in its individual and small group markets for the 2022 benefit year, stating that the HHS-operated risk adjustment program has not worked properly in Alabama's markets and that

¹⁰⁸ Alabama's individual market request is for a 50 percent reduction to risk adjustment transfers for its individual market non-catastrophic and catastrophic risk pools.

¹⁰⁹ Due to the COVID-19 PHE, we permitted states seeking to request a reduction in risk adjustment transfers for the 2022 benefit year an extension until September 1, 2020 to submit such request.

states are best suited to decide whether an adjustment is necessary in their market risk pools. Several other commenters opposed Alabama's request, stating that the state did not meet its burden to substantiate such request, that state flexibility should not be permitted, and that states seeking a reduction in risk adjustment state transfers should operate their own risk adjustment program. Many commenters opposed to Alabama's request expressed more concern with the transfer reduction request for the individual market compared to the small group market. One commenter stated that there was no mathematical reason why the presence of one large issuer would preclude HHS-operated risk adjustment from functioning appropriately in Alabama.

Response: In the 2019 Payment Notice, HHS provided the flexibility for states to request a reduction in risk adjustment state transfers calculated by HHS under the state payment transfer formula when a state elects not to operate the risk adjustment program. We reviewed Alabama's requests and supporting documentation regarding the state's individual and small group market dynamics that it believes warrant an adjustment to the HHS-calculated risk adjustment individual (including catastrophic and non-catastrophic) and small group market transfers under the state payment transfer formula for the 2022 benefit year. Alabama state regulators noted they do not assert that the HHS risk adjustment formula is flawed, only that it results in imprecise results in Alabama's markets that could further reduce competition and increase costs for consumers. The state regulators provided information demonstrating that the request would have a *de minimis* impact on necessary premium increases in both the individual and small group markets for payment issuers, consistent with § 153.320(d)(1)(iii) and (d)(4)(i)(B). HHS analyzed the information provided by the state in support of its request, along with additional data and information available to HHS and the public comments submitted during the comment period on the proposed rule, separately by market and found that the request meets *de minimis* regulatory standard in both markets. While we recognize the comments expressing more concern with the reduction request for the individual market and questioning how the presence of one large issuer would impact how the HHS-operated risk adjustment program functions in Alabama, we did not

propose and are not finalizing any changes to the general framework or review standards under § 153.320(d). As such, a state is permitted to pursue these reduction requests for the individual, small group, or merged market risk pools if the applicable regulatory requirements are met. In this instance, Alabama's individual and small group market requests both met the applicable regulatory requirements; therefore, HHS is approving Alabama's requested reductions to 2022 benefit year transfers calculated under the state payment transfer formula.

Comment: Some commenters asserted that the evidence provided by Alabama does not substantiate the individual market request. One commenter requested that HHS conduct its own comprehensive actuarial analysis of the evidence provided by Alabama and further noted that the 2018 and 2019 risk adjustment results provided by Alabama in support of the request may not be indicative of 2022 transfers, as the past results do not take into account the changes to the HHS risk adjustment models applicable beginning with the 2020 and 2021 benefit years or the proposed changes outlined in the 2022 Payment Notice proposed rule. Another commenter stated that Alabama's suggestion that transfers were difficult to predict is inaccurate.

Response: The evidence provided by Alabama in support of its requests to reduce risk adjustment state transfers by 50 percent in its individual and small group markets was sufficient to justify its request under the *de minimis* requirement for HHS approval under 45 CFR 153.320(d)(4)(i)(B). We further note that Alabama requested that, consistent with 45 CFR 153.320(d), HHS not publish certain information in support of its request because it contained trade secrets or confidential commercial or financial information. 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 only make available on the CMS website 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.¹¹⁰ Consistent with the state's request, we therefore posted a redacted version of the supporting evidence for Alabama's request. However, we note that HHS reviewed the state's un-redacted supporting analysis in evaluating Alabama's request, along with other plan-level data available to HHS and the relevant public comments submitted within the applicable comment period for the proposed rule. We conducted a comprehensive analysis of the available information and found the supporting evidence submitted by Alabama to be sufficient for us to determine the validity of Alabama's 2022 benefit year requests. We also evaluated the comments timely submitted, and determined whether the state's requests met the applicable criteria for approval.

We recognize there is some level of uncertainty regarding future market dynamics, including their potential impact on future benefit year transfers. However, to align with the annual pricing cycle for health insurance coverage, the applicable risk adjustment parameters (including approval or denial of state flexibility reduction requests) must generally be finalized sufficiently in advance of the applicable benefit year to allow issuers to consider such information when setting rates. As such, there will always be an opportunity for some uncertainty regarding the precise impact of future methodological changes (such as the risk adjustment model changes applicable beginning with the 2020 and 2021 benefit years) or unforeseen events (such as the COVID-19 PHE and its impact on enrollment and utilization). With respect to Alabama's 2022 benefit year requests, HHS believes that the evidence submitted by Alabama in support of its transfer reduction requests was sufficient, along with other information available to HHS and timely submitted comments, for HHS to review and confirm that the requests meet the criteria for approval set forth in § 153.320(d)(4)(i)(B).

Comment: Some commenters stated that the reduction requests would diminish the effectiveness of the HHS-operated risk adjustment program and suggested that Alabama set up

¹¹⁰ See 45 CFR 153.320(d)(3).

its own risk adjustment program if it does not believe the HHS-operated risk adjustment program is appropriate for its markets.

Response: We agree that states that do not believe the HHS program is appropriate for its markets can and should consider operating their own state risk adjustment program with a federally-certified alternate risk adjustment methodology tailored to their market risk pools. However, as detailed in the proposed rule and the 2019 Payment Notice, we adopted the state flexibility reduction request regulations in response to specific feedback from certain states, and under our current regulations, it is appropriate to extend this flexibility for the 2022 benefit year. In addition, the approval criteria codified in 45 CFR 153.320(d)(4) are intended to ensure that approved adjustments do not diminish the effectiveness of the HHS-operated risk adjustment program. As part of our assessment of state flexibility requests, we consider the potential impact on the effectiveness of the HHS-operated risk adjustment program for the applicable state market risk pools. We also intend to continue to analyze the impact of state flexibility requests and may propose changes or solicit comments on potential changes for future benefit years.

Comment: A few commenters stated that the approval of the requests would result in increased adverse selection, especially in the individual market. One of these commenters asserted that the reduction request in the individual market would result in a premium increase of more than 1 percent. This commenter also asserted that approval of the reduction request in the individual market would make it difficult for issuers to offer individual market plans with broad networks.

Response: We appreciate commenters' concerns and generally agree that adverse selection concerns are heightened in the individual market, as enrollees typically have higher actuarial risk, risk selection, and risk segmentation in plan selection than those enrolled in the small group market. However, in this case, Alabama has met the criteria for approval at 45 CFR 153.320(d)(4)(i)(B) for both its individual and small group market requests.

In addition, these commenters did not provide any data or supporting evidence during the public comment period to support their assertions. Our analysis 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, showed that the transfer reduction requested by Alabama would have *de minimis* impact on the premiums to cover the difference in transfers for issuers that would receive reduced transfer payments. That is, approval of the request would not result in an increase in premiums of more than 1 percent. HHS does not believe that a change in transfers small enough to have a *de minimis* impact on premiums should affect issuers' operations, such as changes to its provider networks. Therefore, after consideration of the information submitted in support of the state's request and other data and information available to HHS, we find that the evidence provided substantiates the reduction request in both the individual and small group markets and meets the regulatory requirements for HHS approval under 45 CFR 153.320(d)(4)(i)(B).

Based on our review of the comments received on the proposed state flexibility reduction requests within the comment period and HHS's analysis of the requests submitted by Alabama, HHS is granting Alabama's requests to reduce risk adjustment transfers in the individual (including catastrophic and non-catastrophic risk pools) and small group markets by 50 percent for the 2022 benefit year. Therefore, the 50 percent reduction will be applied to the 2022 benefit year plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation above) for the Alabama individual and small group markets.

b. Multi-Year State Flexibility Requests

We proposed several amendments to § 153.320(d) to allow states to request a reduction to otherwise applicable risk adjustment calculations under the state payment transfer formula for up to 3 years, beginning with the 2023 benefit year. Under current policy, states seeking to reduce risk adjustment state transfers in one or more of their market risk pools must submit a request to HHS each year describing the nature of their request and providing supporting

documentation. HHS then reviews the request, sets forth the request in the applicable benefit year's HHS notice of benefit and payment parameters, and approves or denies it based on the evidence and analysis provided by the state in the request and the comments received to the applicable benefit year's proposed HHS notice of benefit and payment parameters.

Under § 153.320(d)(1), states must submit this request annually, and HHS publishes state requests in the applicable benefit year's proposed and final annual HHS notice of benefit and payment parameters. Stakeholders have requested that HHS allow states to request multi-year risk adjustment flexibility reductions. In recognition of these comments, we proposed to provide the flexibility for states to request a reduction to otherwise applicable risk adjustment state transfers under the HHS-operated risk adjustment methodology's state payment transfer formula for up to 3 years beginning with the 2023 benefit year.¹¹¹

We are not finalizing the proposed policies or accompanying proposed updates to § 153.320(d) to permit states to pursue multi-year state flexibility reduction requests. We are maintaining the existing language and framework, which permits states to submit annual requests to reduce the otherwise applicable risk adjustment calculations under the state payment transfer formula for its individual and small group (or merged) markets for a given benefit year to more precisely account for state-specific factors or other unique market characteristics.

We received public comments on the proposed policies and updates to § 153.320(d) to permit states to seek multi-year state flexibility requests for up to 3 years. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal to permit states to request reductions in otherwise applicable risk adjustment state transfers for up to three benefit years, stating that multi-year state flexibility requests would promote stability and competition in the affected state market risk pool(s) and would reduce burden on states and HHS. However, several

¹¹¹ See 85 FR at 78599 – 78601 for details on the proposed updates to § 153.320(d) to permit states to seek multi-year state flexibility requests for up to 3 years.

other commenters opposed this proposal, asserting that states would not be able to accurately or reliably anticipate state market risk pool conditions or market dynamics that far into the future in order for HHS to provide sufficient support for multi-year reduction requests. These commenters also raised the same concerns raised to the Alabama request above, including that the proposal would undermine the effectiveness of the HHS-operated risk adjustment program and result in risk selection, market destabilization, higher premiums, and narrow or restricted provider networks. These commenters noted that states can run their own risk adjustment program if they believe the HHS-operated program does not function properly in their market risk pool(s). One commenter also noted that inadequate advance notice of HHS's decision to terminate or modify the request based on new available information could disrupt rate setting.

Response: We are not finalizing these proposed policies or the updates to § 153.320(d), as we agree with commenters that there are concerns and barriers to multi-year state flexibility reduction requests. We agree that state market conditions, including enrollment and new entrants and exits to the market, can change significantly over 3 years, and three-year reduction requests could destabilize the market if conditions significantly change during the request's approval period. While our proposed framework included mechanisms to address such situations (for example, the proposed process and authority for HHS to terminate or modify a previously approved multi-year request during any one of the subsequent years during the approval period if additional data or new information did not support the continuation of the state's reduction request and the state did not provide sufficient supplemental evidence to rebut such data or information), we agree that further consideration of these types of issues is warranted before pursuing these proposals to permit multi-year state flexibility reduction requests. We are maintaining the existing language and framework in § 153.320(d), which currently permits states to submit annual requests to reduce the otherwise applicable risk adjustment calculations under the state payment transfer formula for its individual and small group (including merged) markets

for a given benefit year to more precisely account for state-specific factors or other unique market characteristics.

After consideration of the comments on the policies and changes related to the multi-year state flexibility reduction requests, we are not finalizing the proposals or changes to § 153.320(d) related to such requests.

4. Audits and Compliance Reviews of Issuers of Reinsurance-eligible Plans (§ 153.410(d)) and Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

a. Audits and Compliance Reviews of Issuers of Reinsurance-eligible Plans (§ 153.410(d))

HHS recently completed the 2014 benefit year audits of a sample of issuers of ACA transitional reinsurance-eligible plans. During this process, HHS encountered significant challenges that impeded its ability to efficiently administer and complete the audits. More specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion from some issuers, and had difficulty obtaining data from these issuers in a format that was usable by HHS. HHS is of the view that codifying additional audit requirements and parameters is an appropriate and necessary measure to ensure that 2015 and 2016 benefit year audits of ACA transitional reinsurance-eligible plans appropriately function to protect the integrity of our programs.

We proposed several amendments to § 153.410(d) to provide more clarity around the audit requirements for issuers of reinsurance-eligible plans. As proposed, the amendments explain the audit process, including what it means to properly comply with an audit and the consequences for failing to comply with audit requirements. We also proposed to expand the oversight tools available to HHS to also provide authority for HHS to conduct compliance reviews of issuers of reinsurance-eligible plans to assess compliance with the applicable requirements of subparts E and H of part 153. We explained that the proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating

in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming reinsurance-eligible plans' compliance with the standards related to reinsurance payments in subparts E and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.¹¹² For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we proposed to codify in the amendments to § 153.410(d) would apply to all issuers of reinsurance-eligible plans. We believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random and targeted auditing of issuers of reinsurance-eligible plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue, but were not selected for audit in the year in question.

Specifically, we proposed to rename § 153.410(d) to “Audits and Compliance Reviews” in order to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate issuers of reinsurance-eligible plans' compliance with the applicable requirements in subparts E and H of part 153. We similarly proposed to update the introductory language in § 153.410(d) to incorporate a reference to HHS compliance reviews and to note that we would conduct these compliance reviews consistent with the standards set forth in § 156.715.

We also proposed to amend the existing introductory language in § 153.410(d) to remove the last sentence that discusses audit results and the accompanying requirements that an issuer must follow if an audit results in a finding of material weakness or significant deficiency. Additionally, as detailed further below, we proposed to replace this with a new proposed framework that captures more details on the audit process and requirements for reinsurance-

¹¹² For further details, please see 78 FR 65100.

eligible plans. As amended, the introductory language at § 153.410(d) would reflect the authority for HHS, or its designee, to audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of subparts E and H of part 153. We also proposed to move the existing introductory language in paragraph (d) requiring an issuer to ensure its relevant contractors, subcontractors, and agents cooperate with audits to a new proposed section, as detailed further below.

Also at § 153.410, we proposed to add new paragraph (d)(1) to establish notice and conference requirements for these audits. The introductory language in proposed paragraph (d)(1) reflects that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan. In proposed paragraph (d)(1)(i), we proposed to codify that all audits under this section would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Further, we proposed to amend § 153.410(d) to add a new paragraph (d)(2) to capture the requirements issuers must meet to comply with an audit under this section. In proposed paragraph (d)(2)(i), we proposed to capture the requirement that currently appears in the introductory text of paragraph (d) for the issuer to ensure that its relevant contractors, subcontractors, and agents cooperate with any audit or compliance review under this section and also proposed to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In new proposed paragraph (d)(2)(ii), we proposed to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit. We explained that such data would need to support the appropriateness and accuracy of the reinsurance payments under review as part of the audit. For example, HHS may request that issuers of reinsurance-eligible plans provide enrollment and claims files, plan reference data, and associated enrollee data sufficient to show that reinsurance payments received were appropriate.

HHS encountered significant challenges in the 2014 benefit year audits when some issuers submitted data in a format that was not readable by HHS. To address this issue, we proposed in new paragraph (d)(2)(ii) that issuers must submit audit data in the format and manner specified by HHS no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (d)(1)(i). For example, HHS may require issuers to submit the requested audit data via Electronic File Transfer. Additionally, under proposed paragraph (d)(2)(iii), HHS proposed to require that issuers respond to any audit notices, letters, request, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We noted that we believe that the proposed requirements in paragraph (d)(2) are necessary and appropriate to ensure the timely completion of audits and to prevent waste that results from repeated, fruitless attempts by HHS to obtain data.

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.410(d)(2)(ii) or (iii), as applicable, we proposed to also add a new paragraph (d)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an extension, we proposed to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraphs (d)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

Under § 153.410(d)(3), HHS proposed it would share its preliminary audit findings with the issuer, and further proposed that the issuer would then have 30 calendar days to respond to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary

audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we proposed at paragraph (d)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. We proposed in paragraph (d)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

We proposed to add a new paragraph § 153.410(d)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We noted that the actions set forth in the final audit report could require an issuer to return reinsurance payments. We maintained the regulatory requirements related to corrective action plans for reinsurance audits that currently appear in paragraph (d) in proposed paragraph (d)(4), which stated that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.410(d), HHS proposed in paragraph (d)(5)(i) that HHS would notify the issuer of reinsurance payments received that the issuer has not adequately substantiated, and under proposed paragraph (d)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. We explained that under this framework, the

continued failure to comply with the audit requirements and provide the necessary information to substantiate the payments made could result in HHS recouping up to 100 percent of the reinsurance payments made to an issuer for the applicable benefit year(s) that are the subject of the audit.

We also clarified that reinsurance payment amounts recovered by HHS as a result of an audit under § 153.410(d) would be allocated, on a pro rata basis, as further payments to the U.S. Treasury under section 1341(b)(3)(B)(iv) of the ACA and further reimbursement of administrative expenses related to operating the reinsurance program under section 1341(b)(3)(B)(ii) of the ACA.¹¹³

We sought comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, inquiries, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests. We are finalizing the proposed updates to the audit and compliance reviews of issuers of reinsurance eligible plans in § 153.410(d), with modifications to certain audit timelines in response to comments stating that issuers would need more time to provide complete and accurate data for an audit and respond to HHS requests.

We received public comments on the proposed updates to audits and compliance reviews of issuers of reinsurance-eligible plans (§ 153.410(d)). The majority of the comments we received to this section were general comments that were also applicable to the similar amendments proposed in the below sections regarding audits and compliance reviews of issuers of risk adjustment covered plans (§ 153.620(c)) and audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)). We responded to these generally applicable comments in the below section on audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)).

¹¹³ See the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30257 through 30259 (May 27, 2014).

What follows is a summary and our responses to the comments we received that were specific to audits and compliance reviews of issuers of reinsurance-eligible plans.

Comment: A few commenters were concerned that HHS is still conducting audits of issuers of reinsurance-eligible plans for monies received more than 5 years ago for a program that ended after the 2016 benefit year. These commenters asked that HHS reconsider the overall approach and need for conducting audits of issuers of reinsurance-eligible plans.

Response: HHS has the authority¹¹⁴ and the responsibility to audit issuers of reinsurance-eligible plans to protect the integrity of the reinsurance program and ensure issuers received the appropriate reinsurance payments during the 2014 through 2016 benefit years. We recognize that the program ended with the 2016 benefit year, but activities related to the operation of the program continued for several years. For example, the final deadline for remittance of 2016 benefit year reinsurance contributions was not until November 2017¹¹⁵ and the last payments to issuers of reinsurance eligible plans were made in Spring 2018. Activities, such as these audits, continue as HHS closes out the program. We are planning to combine reinsurance program audits for the 2015 and 2016 benefit years, which will help facilitate a more efficient audit process and allow HHS to end the audits of reinsurance-eligible plans more quickly. We will similarly look for ways to combine efforts for compliance reviews of reinsurance-eligible plans, should we determine it is necessary or appropriate to pursue those additional oversight measures.

After consideration of the comments related to the proposals regarding audits and compliance review of reinsurance-eligible plans, we are finalizing these provisions as proposed, with slight modifications to certain audit timelines in response to comments¹¹⁶ stating that issuers need more time during audits to provide complete and accurate data and respond to HHS

¹¹⁴ 45 CFR 153.410(d).

¹¹⁵ <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/The-Transitional-Reinsurance-Program/2016-Benefit-Year-Page>.

¹¹⁶ These comments, along with the other general comments submitted on the parallel amendments to the sections on audits and compliance reviews of reinsurance-eligible plans, risk adjustment covered plans, and QHP issuer compliance with federal standards for APTC, CSRs, and user fees, are summarized and responded to in the below preamble section on audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)).

requests. As finalized at § 153.410(d)(1), HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan, rather than the proposed 15 calendar days. Additionally, as finalized at § 153.410(d)(4)(i), if HHS determines the need for a corrective action plan as the result of an audit, issuers must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar days.

We also clarify that we will recoup monies owed due to a finding as the result of an audit of a reinsurance-eligible plan using the same method with which we collect all debts. That is, to recoup the amount identified in § 153.410(d)(5)(i), we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt (if any was owed).

b. Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans
(§ 153.620(c))

Although currently HHS primarily uses the HHS-RADV process to audit issuers of risk adjustment covered plans, § 153.620(c) provides HHS with the authority to conduct audits of issuers of risk adjustment-covered plans outside of the HHS-RADV process. HHS intends to begin audits of issuers of risk adjustment covered plans to ensure the proper payment of high-cost risk pool payments and confirm compliance with applicable requirements. As such, similar to the proposals related to audits and compliance reviews of issuers of reinsurance-eligible plans and learning from our experience with those 2014 benefit year audits, we proposed to provide more clarity around the audit requirements for issuers of risk adjustment covered plans. These proposals sought to explain the audit process, including what it means to properly comply with an audit and the consequences for failing to comply with such requirements.

We also proposed to expand the oversight tools available to HHS beyond traditional audits to also provide authority for HHS to conduct compliance reviews of risk adjustment covered plans to assess compliance with the applicable requirements of subparts G and H of part 153. We explained that the proposed HHS compliance reviews would follow the standards set

forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming risk adjustment covered plans' compliance with the applicable requirements related to the risk adjustment program in subparts G and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.¹¹⁷ For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we proposed to codify in the amendments to § 153.620(c) would apply to all issuers of risk adjustment covered plans. We explained that we believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of issuers of risk adjustment covered plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. As noted in the proposed rule, we anticipate focusing our audit and compliance review activities under § 153.620(c) on ensuring compliance with requirements applicable to the high-cost risk pool payments under the HHS risk adjustment methodology.

Specifically, we proposed to rename § 153.620(c) to “Audits and Compliance Reviews” to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate risk adjustment covered plans' compliance with the applicable requirements in subparts G and H of part 153. We similarly proposed to update the introductory language in paragraph (c) to incorporate a reference to HHS compliance reviews and to note that we would conduct these compliance reviews consistent with the standards set forth in 45 CFR 156.715.

¹¹⁷ For further details, please see 78 FR 65100.

We also proposed to amend the existing introductory language in § 153.620(c) to remove the last sentence that discusses audit results and the accompanying requirements that an issuer must follow if an audit results in a finding of material weakness or significant deficiency. As detailed further below, we proposed to replace this with a new proposed framework that captures more details on the audit process and requirements for risk adjustment covered plans. As amended, the introductory language at paragraph (c) would reflect the authority for HHS or its designee to audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with the applicable requirements of subparts G and H of part 153. We also proposed to move the existing introductory language in paragraph (c) requiring an issuer to ensure its relevant contractors, subcontractors, and agents cooperate with audits to a new proposed section, as described further below.

We proposed to add new paragraph (c)(1) to establish notice and conference requirements for these audits. The introductory language in proposed paragraph (c)(1) reflects that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan. In proposed paragraph (c)(1)(i), we proposed to codify that all audits under this section would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Further, we proposed to amend § 153.620(c) to add paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. In proposed paragraph (c)(2)(i), we would capture the requirement that currently appears in the introductory text of paragraph (c) for the issuer to ensure that its relevant agents, contractors, and subcontractors cooperate with any audit or compliance review under this section and also proposed to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In proposed paragraph (c)(2)(ii), we proposed to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit. We

explained that such data would need to support the appropriateness and accuracy of the risk adjustment transfers (including high-cost risk pool payments and charges) under review as part of the audit. For example, HHS may request that issuers of risk adjustment covered plans provide enrollment and claims files and plan reference data and associated enrollee data.

In new paragraph (c)(2)(ii), we proposed that issuers must submit audit data, in the format and manner specified by HHS, no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (c)(1)(i). For example, HHS may require issuers to submit the requested audit data via Electronic File Transfer. Additionally, under proposed paragraph (c)(2)(iii), HHS proposed to require that issuers respond to any audit notices, letters, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We noted that we believe that the proposed requirements in paragraph (c)(2) are necessary and appropriate to ensure the timely completion of audits and to prevent waste that results from repeated, fruitless attempts by HHS to obtain necessary data.

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.620(c)(2)(ii) or (iii), as applicable, we proposed to also add a new paragraph (c)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an extension, we proposed to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraph (c)(2)(ii) or (iii). The written request would be required to detail the reasons for the extension request and the good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

Under § 153.620(c)(3), HHS proposed that it would share its preliminary audit findings with the issuer, and further proposed that the issuer would then have 30 calendar days to respond

to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we proposed under paragraph (c)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. We proposed under paragraph (c)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

HHS proposed to add a new § 153.620(c)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We noted that the actions set forth in the final audit reports could require an issuer to return risk adjustment (including high-cost risk pool) payments, or pay increased risk adjustment (including high-cost risk pool) charges. We maintained the regulatory requirements for corrective action plans for risk adjustment (including high-cost risk pool) audits that currently appear in § 153.620(c) in proposed paragraph (c)(4), which stated that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.620(c)(2), HHS proposed in paragraph (c)(5)(i) that HHS would notify the issuer of

payments received that the issuer has not adequately substantiated, and in proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. We explained that under this framework, the continued failure to comply with the audit requirements and provide the necessary information to substantiate the transfer amounts under review could result in HHS recouping up to 100 percent of the risk adjustment (including high-cost risk pool) payments, or increased risk adjustment (including high-cost risk pool) charges, made to an issuer for the applicable benefit year(s) that are the subject of the audit.

We noted that any risk adjustment payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool in the applicable benefit year.¹¹⁸ We noted that any high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis to other issuers in the relevant national market in the form of a reduced high-cost risk pool charge in the applicable benefit year. HHS would not, however, re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c).

We sought comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests. We are finalizing the proposed updates to the audit and compliance reviews of issuers of risk adjustment covered plans in § 153.620(c), with modifications to certain audit timelines in response to comments stating that issuers would need more time to provide complete and accurate data for an audit and respond to HHS requests. We will also adopt the approach outlined for distribution of risk adjustment payments or charges under the state

¹¹⁸ See the 2016 Payment Notice final rule, 80 FR 10780 – 10781.

payment transfer formula recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool in the applicable benefit year.¹¹⁹ We also reaffirm that HHS would not re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c). However, after consideration of comments and further evaluation, we are not finalizing our proposal to disburse high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan on a pro rata basis to other issuers in the relevant national market in the form of a reduced high-cost risk pool charge for the same applicable benefit year. We are continuing to consider options and the best possible process to disburse such amounts and will set forth any proposed process in future notice-and-comment rulemaking.

We received public comments on the proposed updates to audits and compliance reviews of issuers of risk adjustment covered plans (§ 153.620(c)). The majority of the comments we received to this section were general comments that were also applicable to the similar amendments proposed in the sections regarding audits and compliance reviews of issuers of reinsurance-eligible plans (§ 153.410(d)) and audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)). We responded to these generally applicable comments in the below section regarding audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)). We received one comment specific to audits and compliance reviews of issuers of risk adjustment covered plans, and the following is a summary of this comment and our response.

Comment: One commenter asked for clarification on the distribution of risk adjustment amounts that are recovered as the result of an audit and may be due to an issuer that is no longer in business.

¹¹⁹ Ibid.

Response: As noted above, we will disburse risk adjustment payments or charges under the state payment transfer formula recovered by HHS during a risk adjustment audit on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool benefit year. As such, we will allocate state payment transfer amounts (payments or charges) recovered by HHS during an audit under § 153.620(c) among the other plans in the impacted state market risk pool(s) proportional to each plan's relative revenue requirement as calculated under the state payment transfer formula relative to the market average of these products.¹²⁰ HHS will pursue options to make payments to all of the appropriate issuers, including those that may no longer be operating in the relevant market. As for disbursing high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan, we are continuing to consider options and the best possible process to disburse high-cost risk pool payments or charges and will set forth any proposed process in future notice-and-comment rulemaking. For example, we may propose in future notice-and-comment rulemaking a recoupment disbursement methodology that provides eligible issuers participating in the current benefit year with a reduction in high-cost risk pool charges.

After consideration of comments on these proposals, we are finalizing the majority of the audit and compliance review provisions as proposed, with slight modifications to certain audits timelines in response to comments¹²¹ stating that issuers need more time during audits to provide complete and accurate data and respond to HHS requests. As finalized at § 153.620(c)(1), HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan, rather than the proposed 15 calendar days. Additionally, HHS is finalizing at § 153.620(c)(4)(i) that if HHS determines the need for a corrective action plan as

¹²⁰ See the 2016 Payment Notice final rule, 80 FR 10780 – 10781

¹²¹ These comments, along with the other general comments submitted on the parallel amendments to the sections on audits and compliance reviews of reinsurance-eligible plans, risk adjustment covered plans, and QHP issuer compliance with federal standards for APTC, CSRs, and user fees, are summarized and responded to in the below preamble section on audits and compliance reviews of APTC, CSRs, and user fees (§ 156.480(c)).

the result of an audit, issuers must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the 30 calendar days that currently appears at § 153.620(c)(1) and was proposed at § 153.620(c)(4)(i). We adopt the proposed approach for distribution of risk adjustment payments or charges under the state payment transfer formula recovered by HHS during an audit of a risk adjustment covered plan and will pay those amounts on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool in the applicable benefit year.¹²² We reaffirm that HHS will not re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c). As stated above, based on comments received and after further evaluation, we are not finalizing our disbursement proposal for high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan and intend to address this issue in future rulemaking.

Finally, we clarify that we will recoup monies owed due to a finding as the result of an audit of a risk adjustment covered plan using the same method with which we collect all debts. That is, to recoup the amount identified in § 153.620(d)(5)(i), we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt (if any is owed).

5. EDGE Discrepancy Materiality Threshold

As stated in § 153.710(a) through (c), an issuer of a risk adjustment covered plan must provide to HHS, through their EDGE server,¹²³ access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS for a benefit year. Consistent with § 153.730, to be considered for risk adjustment payments and charges, issuers of risk adjustment covered plans must submit their respective EDGE data by April 30 of the year

¹²² See the 2016 Payment Notice final rule, 80 FR 10780 – 10781.

¹²³ This is also known as the dedicated distributed data collection environment.

following the applicable benefit year. At the end of the EDGE data submission process, HHS issues final EDGE server reports¹²⁴ which reflect an issuer's data that was successfully submitted by the data submission deadline. Within 15 calendar days of the date of these final EDGE server reports, the issuer must confirm to HHS that the information in the final EDGE server reports accurately reflect the data to which the issuer has provided access to HHS through its EDGE server for the applicable benefit year by submitting an attestation; or the issuer must describe to HHS any discrepancies it identifies in the final EDGE server reports.

HHS reviews all reported EDGE discrepancies to evaluate the implications of each incorrect data submission for risk adjustment transfers and risk adjustment data validation. For risk adjustment transfers calculated under the state payment transfer formula, HHS evaluates whether the reported EDGE discrepancy is material and has a process to address incorrect EDGE data submissions that have a material impact on risk adjustment transfers for a state market risk pool.^{125,126} Currently, HHS uses the same materiality threshold for reconsideration requests set forth in § 156.1220(a)(2) for determining whether the EDGE discrepancy has a material impact on the risk adjustment transfers calculated under the state payment transfer formula. Consequently, the reported EDGE discrepancy is considered material if the amount in dispute is equal to or exceeds the lower of either \$10,000 or one percent of the total estimated transfers in the applicable state market risk pool. After analyzing reported EDGE discrepancies in prior benefit years, we proposed to codify a materiality threshold for EDGE discrepancies and also

¹²⁴ These reports are: Enrollee (Without) Claims Summary (ECS), Enrollee (Without) Claims Detail (ECD), Frequency Report by Data Element for Medical Accepted Files (FDEMAF), Frequency Report by Data Element for Pharmacy Accepted Files (FDEPAF), Frequency Report by Data Element for Supplemental Accepted Files (FDESAF), Frequency Report by Data Element for Enrollment Accepted Files (FDEEAF), Claim and Enrollee Frequency Report (CEFR), High Cost Risk Pool Summary (HCRPS), High Cost Risk Pool Detail Enrollee (HCRPDE), Risk Adjustment Claims Selection Summary (RACSS), Risk Adjustment Claims Selection Detail (RACSD), Risk Adjustment Transfer Elements Extract (RATEE), Risk Adjustment Risk Score Summary (RARSS), Risk Adjustment Risk Score Detail (RARSD), Risk Adjustment Data Validation Population Summary Statistics (RADVPS), Risk Adjustment Payment Hierarchical Condition Category Enrollee (RAPHCCER), Risk Adjustment User Fee (RAUF).

¹²⁵ See, for example, <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2019-QQ-Guidance.pdf>. Also see 83 FR 16970 through 16971.

¹²⁶ HHS may also take action on reported material EDGE discrepancy if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

proposed to establish a higher materiality threshold for EDGE discrepancies. More specifically, we proposed the following materiality threshold for EDGE discrepancies: the amount in dispute must equal or exceed \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less.¹²⁷ Where an identified material EDGE discrepancy negatively affects the issuer without having a negative effect on other issuers within the state market risk pool, issuers would be required to adhere to the initial data submission and accept the consequences of the data submission, even when the monetary impact of the inaccuracy on the issuer submitting incorrect data is potentially substantial. Therefore, HHS would generally only take action on material discrepancies that harm other issuers in the same state market risk pool.¹²⁸ In general we expect about half of discrepancies that are material under previous criteria would no longer be material under the new criteria.

We proposed to amend § 153.710, by creating new paragraph (e) and redesignating paragraphs (e), (f) and (g), as (f), (g) and (h) respectively, to capture the proposed EDGE discrepancy materiality threshold and proposed to apply it beginning with the 2020 benefit year.¹²⁹ We explained that we believe this increased materiality threshold will reduce burden on issuers having to submit additional data to HHS when a discrepancy is determined to be potentially material and allow more certainty and stability for risk adjustment transfers. If a reported EDGE discrepancy is determined to not meet the materiality threshold, HHS would take no action on the discrepancy and the issuer's data submission would remain as submitted by the data submission deadline for the applicable benefit year.

We also explained that while HHS generally only takes action on reported material EDGE discrepancies that are determined to harm other issuers, issuers must continue to report

¹²⁷ We are not proposing any changes to the materiality threshold for reconsideration requests in § 156.1220(a)(2).

¹²⁸ Consistent with the current process, HHS may also take action on reported material EDGE discrepancies if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

¹²⁹ The deadline for submission of 2020 benefit year risk adjustment data is April 30, 2021. See 45 CFR 153.730. As such, the EDGE discrepancy reporting process for the 2020 benefit year will not begin until May 2021.

and describe any identified EDGE discrepancy to HHS in a format specified by HHS for each benefit year. Issuers must report all data discrepancies in order to permit HHS to determine whether such an error is material and actionable and to evaluate the impact on other issuers in the state market risk pool. We sought comment on the proposed EDGE discrepancy materiality threshold and the accompanying amendments to § 153.710. We are finalizing the EDGE discrepancy materiality threshold and the amendments to § 153.710 as proposed.

We received public comments on the proposed updates to the EDGE discrepancy materiality threshold. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposed increase to the EDGE discrepancy materiality threshold. These commenters noted the increased threshold amount would enhance program integrity by focusing efforts on discrepancies that negatively impact other issuers in the applicable market risk pool, reduce the administrative burden associated with these data requests, and allow more certainty and stability for risk adjustment transfers. A few commenters expressed the belief that the previous threshold had been too low. One commenter agreed with increasing the threshold but noted they lacked the data to confirm the proposed threshold was appropriate.

Response: We appreciate the support for increasing the EDGE discrepancy materiality threshold. We agree with commenters that the increased discrepancy materiality threshold will reduce issuer burden and allow for more certainty and stability for risk adjustment transfers. We also agree that the current threshold, which was established to be consistent with the materiality threshold for reconsideration requests set forth in 45 CFR 156.1220(a)(2), is too low for discrepancies and most of the time required HHS to reallocate minimal amounts of risk adjustment monies. As such, we are finalizing the EDGE materiality threshold as proposed.

In assessing different EDGE discrepancy materiality thresholds, HHS analyzed the 2017 benefit year EDGE discrepancies. Specifically, we reviewed the discrepancy amounts and impacts on affected issuers in the impacted state market risk pools and considered a variety of

threshold amounts. We found that \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool balanced reducing the number of reallocations involving small amounts with maintaining data integrity and confidence in the risk adjustment program.

After consideration of the comments on these proposals, for the 2020 benefit year and beyond, we are finalizing the EDGE discrepancy materiality threshold as proposed, including the accompanying proposed amendments to § 153.710, to reflect the amount in dispute must equal or exceed \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less. Where an identified material EDGE discrepancy negatively affects the issuer without having a negative effect on other issuers within the state market risk pool, issuers will be required to adhere to the initial data submission and accept the consequences of their data submission, even when the negative financial impact of the inaccuracy on the issuer submitting incorrect data is above this materiality threshold. Therefore, HHS will only take action on material discrepancies that harm other issuers in the same state market risk pool.¹³⁰

6. Risk Adjustment User Fee for 2022 Benefit Year (§ 153.610(f))

If a state is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. As noted previously in this final rule, for the 2022 benefit year, HHS will be operating the risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee.¹³¹ Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a state, 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

¹³⁰ Consistent with the current process, HHS may also take action on reported material EDGE discrepancies if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

¹³¹ 78 FR 15416 through 15417.

specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A-25 established federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(B) of Circular No. A-25 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 2021 Payment Notice, HHS calculated the federal administrative expenses of operating the risk adjustment program for the 2021 benefit year to result in a risk adjustment user fee rate of \$0.25 PMPM based on our estimated costs for risk adjustment operations and estimated billable member months for individuals enrolled in risk adjustment covered plans. For the 2022 benefit year, we proposed to use the same methodology to estimate our administrative expenses to operate the program. These costs cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment program activities. To calculate the user fee, we divided HHS's projected total costs for administering the risk adjustment programs on behalf of states by the expected number of billable member months in risk adjustment covered plans in states where the HHS-operated risk adjustment program will apply in the 2022 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for the 2022 benefit year will be approximately \$60 million, and the risk adjustment user fee would be \$0.25 PMPM. The risk adjustment user fee costs for the 2022 benefit year are

expected to remain steady from the prior 2021 benefit year estimates. However, we project a small decline in billable member months in the individual and small group markets overall in the 2022 benefit year based on the declines observed in the 2019 benefit year. We sought comment on the proposed risk adjustment user fee for the 2022 benefit year. We also explained that we would continue to examine the costs and enrollment projections for the 2022 benefit year, particularly as we receive more information on the impact of the coronavirus disease 2019 (COVID-19) PHE, and proposed to incorporate any such newly available data to update the final 2022 benefit year risk adjustment user fee rate that we would announce in the final rule. We sought comment on these estimates and the use of any newly available data to update the estimates to reflect any emerging cost or enrollment trends for the final 2022 benefit year user fee. We are finalizing the 2022 benefit year risk adjustment user fee as proposed.

We received public comments on the proposed risk adjustment user fee for 2022 benefit year (§ 153.610(f)) and accompanying solicitation of comments. The following is a summary of the comments we received on the proposed 2022 benefit year user fee and our responses.

Comment: One commenter expressed concern regarding HHS's assumption that overall enrollment would decline in the 2022 benefit year, which would result in an increased risk adjustment user fee amount. This commenter requested additional detail on the projected decrease in billable member months.

Response: Our methodology for calculating the 2022 benefit year risk adjustment user fee was the same as the one used for 2021 benefit year. But as the commenter noted, when we proposed the rule, we anticipated a small decline in billable member months in the individual and small group markets overall based on the declines observed in 2019 benefit year. We continue to believe that the finalized rate will ensure adequate funding for HHS to operate the risk adjustment program in all 50 states and the District of Columbia for 2022. Importantly, we also

note that our assumption of a small decline in billable member months did not actually result in any increase in the risk adjustment user fee from the previous 2021 benefit year amount.¹³²

After consideration of the comments on this proposal, we are finalizing the risk adjustment user fee for the 2022 benefit year as \$0.25 PMPM as proposed.

7. Risk Adjustment Data Validation Requirements when HHS Operates Risk Adjustment (HHS-RADV) (§ 153.630)

To ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS-RADV) under §§ 153.350 and 153.630 in any state where HHS is operating risk adjustment on a state's behalf. The purpose of HHS-RADV is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the HHS-operated risk adjustment program. HHS-RADV also ensures that risk adjustment transfers reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor data quality, thereby helping to ensure that the HHS-operated risk adjustment program assess charges to issuers with plans with lower-than-average actuarial risk while making payments to issuer with plans with higher-than-average actuarial risk. HHS-RADV consists of an initial validation audit and a second validation audit.¹³³ Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to the issuer's 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.

¹³² The 2021 benefit year risk adjustment user fee amount is also \$0.25 PMPM. See 85 FR at 29194 - 29195

¹³³ 45 CFR 153.630(a) through (c).

a. Exemptions from HHS-RADV (§ 153.630(g))

In 2020 Payment Notice, we codified several exemptions from the HHS-RADV requirements. In this rule, we proposed to codify the previously established exemption¹³⁴ for issuers who only offer small-group carryover coverage in the state during the benefit year being audited at new proposed § 153.630(g)(4). As we discussed in the 2020 Payment Notice, under this 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 in the state) would be considered an exiting issuer and would be exempt from HHS-RADV for the benefit year with the carry-over coverage.¹³⁵

We also proposed to codify the previously established exemption¹³⁶ for issuers who are the sole issuer in a state market risk pool during the benefit year that is being audited at new proposed § 153.630(g)(5). As we discussed in the 2020 Payment Notice, for single issuer market risk pool(s), there are no risk adjustment transfers calculated under the state payment transfer formula and thus, no payment or financial accountability to other issuers for that risk pool.¹³⁷ As such, a sole issuer in a state market risk pool is not required to participate in the HHS-operated risk adjustment program (except for purposes of high-cost risk pool payments and charges) for that state market risk pool. 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 HHS-RADV for those risk pools with other issuers that had risk adjustment transfers calculated under the state payment transfer formula.

We noted that these exemptions do not introduce new policies; instead, the proposed amendments to § 153.630(g) were simply to codify these previously established exemptions in

¹³⁴ 84 FR 17503 through 17504.

¹³⁵ Ibid.

¹³⁶ 84 FR 17504.

¹³⁷ Ibid.

regulation. We also clarified that any issuer that qualifies for the small group carryover coverage exemption in new proposed paragraph (g)(4) would not have its risk score and its associated risk adjustment transfers adjusted due to its own risk score error rate, as the issuer would not have participated in HHS-RADV for the benefit year in which it only offered the small group carryover coverage. However, that issuer's risk score and resulting risk adjustment transfers could be subject to HHS-RADV adjustments if other issuers in that state market risk pool were outliers and received HHS-RADV risk score error rates for that benefit year.

We solicited comments on these proposals.

We only received comments in support of codifying the HHS-RADV exemption for issuers who are the sole issuer in a state market risk pool during the benefit year being audited and are finalizing the amendment to § 153.630(g)(5) to codify that exemption as proposed. We received several public comments on the codification of the HHS-RADV exemption for issuers providing only small group carryover coverage in the benefit year being audited at § 153.630(g)(4), some of these comments restated the proposal without providing an opinion while others expressed opposition to the proposal. After consideration of the comments received, we are also finalizing the amendment to § 153.630(g)(4) to codify this exemption as proposed.

The following is a summary of the comments we received on the codification of the exemption for issuers providing only small group carryover coverage and our responses.

Comment: Some commenters asked HHS to reconsider the HHS-RADV exemption for issuers providing only small group carryover coverage in the benefit year being audited. These commenters expressed concern that an exiting issuer with only small group carryover coverage may potentially make up a large portion of the market for that calendar year. The commenters also stated that issuers providing only small group carryover coverage, who have not undergone HHS-RADV in the previous 2 years, should still be subject to HHS-RADV requirements for that year.

Response: After reviewing the comments on the proposed amendments to § 153.630(g)(4), we are finalizing, as proposed, the codification of the exemption from HHS-RADV for issuers providing only small group carryover coverage in the benefit year being audited. As discussed above and in the proposed rule, neither of these exemptions are new¹³⁸ and the proposals were to codify the previously established exemptions in regulation. We continue to believe that both exemptions are appropriate.

With respect to the exemption for sole issuers, we believe it is appropriate because 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 thus, there is no payment or financial accountability to other issuers for that risk pool. With respect to the small group carryover coverage exemption, we believe that this exemption ensures that such small group carryover only issuers (who are considered exiting issuers) are treated the same as other exiting issuers with regards to HHS-RADV requirements.

With respect to concerns that issuers seeking to use the small group carryover coverage exemption might make up a large portion of the market, based on our past experience operating HHS-RADV for the 2017 and 2018 benefit years, we found that issuers that would qualify for this exemption criteria are typically very small issuers, with the majority having fewer than 500 billable member months statewide or below \$15 million in total premium. As a result, we do not believe issuers that would qualify for this exemption would make up a large portion of a state's market risk pool and these issuers have generally had a reasonable chance of being exempted under other exemption categories.¹³⁹

With respect to the comment on issuers being subject to HHS-RADV requirements if they have not participated in HHS-RADV in the previous 2 years, we note that generally all issuers of risk adjustment covered plans in a state market risk pool must participate in HHS-RADV unless they qualify for an exemption specified in 153.630(g). As established at

¹³⁸ See 84 FR 17503 through 17504.

¹³⁹ See 45 CFR 153.630(g)(1) and (g)(2).

153.630(g)(2), it is only issuers at or below the materiality threshold that are subject to random and targeted sampling for HHS-RADV participation approximately every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audits). This exemption for issuers at or below materiality threshold was created in response to stakeholder requests to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans. We maintain that this exemption for issuers at or below materiality threshold is important given the fixed costs associated with hiring an initial validation auditor and submitting results to HHS on an annual basis; therefore, we do not intend to make changes to it at this time.

After consideration of the comments received on these proposals, we are finalizing the codification of the sole issuer and small group carryover coverage issuer exemptions from HHS-RADV and the amendments to § 153.630(g) as proposed.

b. IVA Requirements (§ 153.630(b)(3))

In accordance with § 153.630(b)(3), an issuer must ensure that its IVA Entity is reasonably free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question. In prior rulemaking, we explained that to meet this standard, the IVA Entity, among other things, may not have had a role in establishing any relevant internal controls of the issuer related to the risk adjustment data validation process when HHS is operating risk adjustment on behalf of a state, or serve in any capacity as an advisor to the issuer regarding the IVA.¹⁴⁰ In the proposed rule, we proposed to amend this standard and clarify that to demonstrate that the IVA Entity is reasonably free of conflicts, the IVA Entity must also not have or previously have had a role in establishing any relevant internal controls of the issuer related to risk adjustment or the EDGE server data submission process for the applicable benefit year for which the IVA Entity is performing the IVA on behalf of the issuer. Additionally, the IVA Entity must also not have served in any capacity as an advisor to the issuer regarding the risk adjustment or EDGE server data

¹⁴⁰ See 79 FR 13758.

submission for the applicable benefit year. For example, the IVA Entity cannot serve as the issuer's third party administrator (TPA) for purposes of the EDGE data submission for HHS-operated risk adjustment in the 2020 benefit year and serve as the IVA Entity for that issuer for the 2020 benefit year. We proposed these changes because we are concerned about conflicts of interest that could arise if the same entity assists or completes the EDGE data submissions for an issuer for an applicable benefit year, and then also serves as the IVA Entity auditing the submission of that data in HHS-RADV. This proposal was in addition to the requirements set forth in 2014 and 2015 Payment Notices.¹⁴¹ We sought comment on this proposal.

The only comments we received on the proposed updates to IVA requirements (§ 153.630(b)(3)) supported the proposal noting that there is a potential conflict of interest if an IVA Entity for a company also served as the company's TPA for purposes of EDGE data submission or risk adjustment. These commenters were in support of the regulatory change. After consideration of comments on these proposals, we are finalizing this policy and the accompanying amendment to § 153.630(b)(3) as proposed.

c. HHS-RADV Administrative Appeals

In the 2015 Payment Notice, we established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain ACA programs, including the calculation of risk adjustment charges, payments and user fees.¹⁴² In the 2018 Payment Notice final rule, we extended this three-level administrative appeal process to permit issuers to dispute the findings of a second validation audit with respect to the 2016 benefit year HHS-RADV and beyond.¹⁴³ As previously explained, issuers are not permitted to use the discrepancy reporting or administrative appeal processes under §§ 153.630(d)(2) and 156.1220, respectively, to contest

¹⁴¹ The 2014 Payment Notice final rule required that that issuers ensure that IVA Entities are reasonably capable of performing the audit, the audit is completed, the auditor is free from conflicts of interest, and the auditor submits information regarding the IVA to HHS in the manner and timeframe specified by HHS. 78 FR 15410 at 15437. The 2015 Payment Notice final rule established standards and guidelines regarding the qualifications of the IVA Entity, including further details on the conflict of interest standards. 79 FR 13744 at 13758-13759.

¹⁴² 78 FR 13818 through 13820.

¹⁴³ 81 FR 94106.

the IVA findings, because HHS does not conduct the IVA or produce those results.¹⁴⁴ Instead, issuers should review their IVA findings and discuss any concerns with its IVA Entity prior to attesting to and submitting those results to HHS.¹⁴⁵ As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and second validation audit will receive a Second Validation Audit Findings Report, and therefore, have the right to appeal the second validation audit findings.¹⁴⁶ The existing regulation at § 153.630(d)(2) captures this policy. In the proposed rule, we proposed conforming amendments to paragraph (d)(3) to similarly add “if applicable” to the reference to an issuer’s ability to appeal the findings of the second validation audit to ensure these regulatory provisions also appropriately capture this limitation.¹⁴⁷ We sought comment on these proposed amendments.

The only comment we received on the proposal to codify the previously established limits on the ability to appeal SVA findings as part of the HHS-RADV administrative appeals process was in support of the proposed clarifications. After consideration of the comments on this proposal, we are finalizing the conforming amendments to § 153.630(d)(3) as proposed.

d. Timeline for Collection of HHS-RADV Payments and Charges

In the 2020 Payment Notice,¹⁴⁸ we finalized an updated timeline for the publication, collection, and distribution of HHS-RADV adjustments to transfers. This timeline was adopted to allow issuers to report HHS-RADV adjustments in a later MLR reporting year and to consider, in accordance with any guidance from the state DOIs, these adjustments in rate setting during a later benefit year (specifically, the year in which the HHS-RADV adjustments are collected and paid). We proposed, beginning with 2019 benefit year HHS-RADV, to revert to the previous

¹⁴⁴ Ibid.

¹⁴⁵ See, for example, Sections 9.1, 9.5 and 9.7 of the “2017 Benefit Year Protocols ACA HHS Risk Adjustment Data Validation, Version 2.0,” August 10, 2018.

¹⁴⁶ 84 FR 17495. If the pairwise means test results conclude there is sufficient agreement between the IVA and SVA findings, the IVA findings are used to adjust risk scores. Issuers with sufficient pairwise agreement do not receive a Second Validation Audit Findings Report and there are no SVA findings to appeal. See 84 FR at 17495.

¹⁴⁷ As detailed further below, we propose similar conforming amendments to the references to an issuer’s ability to appeal the findings of the second validation audit in 45 CFR 156.1220(a)(1) and (a)(3).

¹⁴⁸ 84 FR 17506 through 17507.

schedule¹⁴⁹ for the collection of HHS-RADV charges and disbursement of payments in the calendar year in which HHS-RADV results are released (for example, collection and disbursement of 2021 benefit year HHS-RADV adjustments would begin in summer or fall of 2023). We are finalizing the change in the HHS-RADV adjustment timeline as proposed.

HHS publishes the final summary report of risk adjustment transfers (without HHS-RADV adjustments) and information on risk adjustment default charges for the applicable benefit year in the summer of the year after the applicable benefit year (typically June 30th of the year after the applicable benefit year), and issuers report those risk adjustment amounts in their MLR reports by July 31st of the year after the applicable benefit year.¹⁵⁰ Payment and collection of these risk adjustment transfer and default charge amounts generally occurs in August and September of the year after the applicable benefit year. We separately report the HHS-RADV adjustments and information on default data validation charges for the applicable benefit year approximately one year after the final summary report of risk adjustment transfers for that benefit year is published (typically 2 years after the applicable benefit year in August¹⁵¹).

Under the HHS-RADV timeline effective prior to the publication of this rule, HHS begins collection and disbursement of HHS-RADV adjustments and default data validation charges and allocations 2 years after announcing the HHS-RADV adjustments (for example, collection and disbursement of 2017 benefit year HHS-RADV adjustments will begin in 2021¹⁵²). For MLR reporting purposes, under the 2020 Payment Notice approach applicable through 2018 benefit year HHS-RADV, issuers will reflect the HHS-RADV adjustment amounts

¹⁴⁹ See 79 FR 13768 and 13769. Also see, for example, Table 3 in the document entitled “Proposed Key Dates for Calendar Year 2019: Qualified Health Plan (QHP) Certification in the Federally-facilitated Exchanges (FFE)s; Rate Review; and Risk Adjustment.” Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Key-Dates-Table-for-CY2019.pdf>.

¹⁵⁰ The one exception is for the rare circumstances that HHS is unable to collect full risk adjustment charges in a state market risk pool or high-cost risk pool charges in a national market risk pool. In such situations, issuers receiving lesser payments can reflect the reductions in their MLR reports.

¹⁵¹ HHS-RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID-19-related delay in HHS-RADV activities for the 2019 benefit year. See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

¹⁵² <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf>.

and default data validation charges and allocations in the MLR reporting year in which collections and payments of those amounts occur. Subject to approval by state DOIs, issuers are also permitted to reflect these amounts in rate setting for the same benefit year in which those amounts are paid or collected. For example, 2017 benefit year HHS-RADV adjustments and default data validation charges and allocations were announced in August 2019 and issuers will report these amounts in the 2021 MLR reporting year (MLR reports filed in 2022), the same year that the adjustments and default data validation charges will be collected and paid. Additionally, subject to permission by state DOIs, issuers were permitted to account for the impacts of those 2017 benefit year HHS-RADV adjustments in rate setting for the 2021 benefit year.

The 2020 Payment Notice timeline was intended to address stakeholder concerns regarding the predictability of HHS-RADV adjustments, especially for the initial payment year. However, since the publication of the 2020 Payment Notice, we have received feedback stating that the extended timeline has not provided the increased flexibility intended by the policy and instead has introduced undue complexity. Specifically, stakeholders have expressed concern that this policy conflicts with state requirements for financial accounting, and can negatively impact their MLR rebate position, particularly if the issuer experiences substantial changes in enrollment over the 3-year MLR calculation period.¹⁵³ Additionally, in the 2020 HHS-RADV Amendments Rule, we finalized a transition from the prospective application of HHS-RADV adjustments¹⁵⁴ to a concurrent application beginning with 2020 benefit year HHS-RADV.¹⁵⁵ More specifically, we finalized a policy to transition to applying HHS-RADV adjustments to the risk scores and transfers of the same benefit year being audited for all issuers (for example, 2021 benefit year HHS-RADV adjustments will apply to 2021 benefit year risk scores and risk adjustment transfers, rather than to 2022 benefit year risk scores and risk adjustment transfers, as

¹⁵³ Issuer MLRs are calculated using a 3-year average. See section 2718(b)(1)(B)(ii) of the Act and 45 CFR 158.220(b).

¹⁵⁴ The exception to the prospective application of HHS-RADV adjustments is for exiting issuers, whose HHS-RADV results are currently used to adjust risk scores and transfers for the benefit year being audited (rather than the following benefit year's transfers). See 83 FR 16965 through 16966 and 84 FR 17503 through 17504.

¹⁵⁵ 85 FR 77002-77005.

would have taken place prior to the finalization of the 2020 HHS-RADV Amendments Rule).¹⁵⁶

To transition to this policy, HHS will average the 2019 and 2020 benefit year HHS-RADV results of non-exiting issuers who participated in risk adjustment for both benefit years¹⁵⁷ to calculate the HHS-RADV adjustment to 2020 benefit year risk scores and transfers, and will publish the HHS-RADV adjustments to transfers along with information on any default data validation charges imposed for both benefit years.¹⁵⁸ Beginning with the 2021 benefit year of HHS-RADV, risk scores and transfers will only be adjusted once based on the same benefit year's HHS-RADV results (that is, 2021 benefit year HHS-RADV results would adjust 2021 benefit year plan liability risk scores).

Although the operational timelines of the risk adjustment program and the nature of HHS-RADV causes HHS-RADV results to always be at least a year behind the associated risk adjustment transfers report, we have continued to consider these issues. The above referenced changes to the benefit year to which HHS-RADV adjustments are applied also lead us to revisit these issues. We adopted the 2020 Payment Notice timeline to provide issuers (and states) with more options on how and when to account for the financial impacts from HHS-RADV. However, as noted above, stakeholder feedback has indicated that the approach did not achieve its policy goal and instead introduced unnecessary complexity. Therefore, we proposed to revert to the previous schedule for collection and disbursement of HHS-RADV adjustments and default data validation charges and begin such activities in the summer or fall of the calendar year in which

¹⁵⁶ Ibid.

¹⁵⁷ Exiting and new issuers who participate in only one of the two benefit years will not have their results for 2019 and 2020 averaged before being applied to the relevant benefit year's transfers. For exiting issuers, positive error rate outlier issuers' 2019 and 2020 HHS-RADV results will be applied to the risk scores and risk adjustment transfers for the benefit year being audited. If a new issuer entered a state market risk pool in 2020, its plan liability risk score(s) and risk adjustment transfer for the 2020 benefit year could be impacted by the new issuer's own 2020 HHS-RADV results, the combined 2019 and 2020 HHS-RADV results of other non-exiting issuers in the same state market risk pool, as well as the 2020 HHS-RADV results of exiting positive error rate outlier issuers in the same state market risk pool.

¹⁵⁸ We note that we intend to publish a separate 2019 benefit year HHS-RADV results memo that will provide an overview of the 2019 benefit year error rate results. We also plan to release a separate 2019 benefit year HHS-RADV Summary Report that details adjustments to 2019 benefit year risk scores and transfers if there are any exiting positive error rate outlier issuers in the 2019 benefit year of HHS-RADV. The average error rate approach is not applicable for these issuers because exiting issuers who participated in 2019 HHS-RADV will not have 2020 benefit year risk scores or transfers to adjust.

HHS-RADV results are released. For example, collection of 2021 benefit year HHS-RADV adjustments and default data validation charges and disbursement of such amounts would begin in summer or fall of 2023. In support of the new proposed timeline for collection and disbursement of HHS-RADV adjustments and default data validation charges, we explained that HHS would need to release the applicable benefit year's report on HHS-RADV adjustments and default data validation charges earlier in the year so the amounts are available for issuers to use for MLR reporting purposes. We therefore also proposed to release the applicable benefit year's HHS-RADV summary report no later than early summer, and require issuers to report those amounts in the MLR reports submitted by July 31st of the same calendar year in which the results are released. For example, as proposed, the summary report on 2021 benefit year HHS-RADV adjustments and default data validation charges and allocations would be released no later than early summer 2023, and issuers would be instructed to report these amounts in the 2022 MLR reporting year (MLR reports that include 2022 benefit year data that are submitted by July 31, 2023; See Table 9). We would then collect and disburse HHS-RADV adjustments and default data validation charges and allocations in summer or fall of the calendar year in which HHS-RADV results are released (for example, collection and disbursement of 2021 benefit year HHS-RADV adjustments and default data validation charges would begin in summer or fall of 2023). We noted that the Unified Rate Review Template (URRT) instructions currently permit issuers and states to consider HHS-RADV impacts in rates for the year when these amounts will be collected and disbursed and specified, as an example, that as 2017 RADV adjustments will be collected in the 2021 calendar year, a state may allow issuers to consider these adjustments in their 2021 rate setting. Therefore, in the proposed rule, we proposed to remove this flexibility from the URRT instructions.

We further explained that the proposed timeline would help mitigate concerns regarding the incongruity with state financial accounting requirements, as well as potential undue impacts of HHS-RADV adjustments on MLR rebate liability, which could result from the HHS-RADV

adjustments being reported outside the 3-year MLR aggregation window and thus potentially distorting the MLR experience of the benefit year to which HHS-RADV adjustments apply. Additionally, we noted this proposed change may also help mitigate the impact of any substantial changes in enrollment between benefit years.

We proposed to begin this policy with the collection and disbursement of HHS-RADV adjustments and default data validation charges for the 2019 benefit year and noted that due to the delay in the 2019 benefit year HHS-RADV,¹⁵⁹ the timing of collections and disbursements is different for the 2019 benefit year. We sought comment on this proposal and whether any consideration should be made in the transition to this policy to account for 2017 and 2018 benefit year HHS-RADV collection and disbursement of payments and charges (under the 2020 Payment Notice timeline) also occurring in 2021 and 2022.

We are finalizing the updates to the timeline for collection of HHS-RADV payments and charges, as proposed. As such, HHS will publish the 2019 and 2020 benefit year HHS-RADV Summary Report for non-exiting issuers in early summer of 2022.^{160,161} Issuers will also be required to include any payments and charges reflected on this report, along with risk adjustment transfers for the 2021 benefit year, in their 2021 MLR reports, which must be filed by July 31, 2022. Issuers will be required to report the 2019 and 2020 benefit year HHS-RADV adjustments to transfers (including default data validation charge and allocation amounts) in their MLR

¹⁵⁹ HHS-RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID-19-related delay in HHS-RADV activities for the 2019 benefit year. See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

¹⁶⁰ In the proposed rule, we proposed to publish separate 2019 and 2020 summary reports in early summer of 2022. However, as noted earlier in this preamble, in the 2020 HHS-RADV Amendments Rule (85 FR 77002-77005), we finalized a transition from the prospective application of HHS-RADV adjustments to a concurrent application beginning with 2020 benefit year HHS-RADV. To effectuate this transition, HHS-RADV adjustments for issuers who participated in both the 2019 and 2020 benefit years will be averaged together and applied to 2020 risk adjustment risk scores. As a result, we will be publishing a single HHS-RADV summary report in calendar year 2022 that details transfer information from both the 2019 and 2020 benefit years of HHS-RADV.

¹⁶¹ Consistent with the current application of HHS-RADV results for exiting issuers identified as positive error rate outliers, issuers who fit this description for 2019 HHS-RADV will have their results applied to the risk scores and transfer amounts for the benefit year being audited, that is, the 2019 benefit year. See the 2020 Payment Notice, 84 FR at 17503-17504. We will publish the 2019 HHS-RADV Summary Report for these issuers (if any) in the 2022 calendar year. Additionally, as finalized in the 2020 Payment Notice, for HHS-RADV benefit years beginning with 2018, HHS only adjusts exiting issuers if they are positive error rate outliers. This policy remains unchanged for the 2019 benefit year and beyond. See the 2020 HHS-RADV Amendments Rule (85 FR at 77003).

reports for the 2021 MLR reporting year (MLR reports that include 2021 benefit year data that are submitted by July 31, 2022). Finally, HHS will begin collecting both 2019¹⁶² and 2020 HHS-RADV adjustments to transfers for non-exiting issuers along with any default data validation charges imposed for these 2 benefit years and disbursing related payments in late summer or early fall of 2022.

We received public comments on the proposed updates to the timeline for collection of HHS-RADV payments and charges. The following is a summary of the comments we received on the proposed updated timeline and our responses.

Comment: Many commenters expressed general support for reverting to the original schedule for the collection and disbursement of HHS-RADV payments and charges.

Commenters largely concurred with HHS that these changes would help resolve incongruities with state financial accounting requirements and potential undue impacts of HHS-RADV adjustments on MLR rebate liability for issuers whose enrollment experiences substantially change over a 3-year period. However, other commenters were concerned about the overlap that would occur during the transition period as issuers would be required to report 2017 benefit year HHS-RADV impacts alongside 2019 and 2020 benefit years HHS-RADV impacts¹⁶³ during 2021 MLR reports (filed in summer 2022) and would be required to report 2018 and 2021 HHS-RADV impacts in their 2022 MLR reports (filed in summer 2023). Some of these commenters requested clarification about how the proposed policy affects reporting of 2017 and 2018 HHS-RADV adjustments, while one commenter suggested that 2017 HHS-RADV be reported in 2020 MLR filings and 2018 HHS-RADV adjustments be reported in 2021 filings. Another commenter

¹⁶² See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo>.

¹⁶³ 2019 HHS-RADV is delayed due to COVID-19 and, as such, results are scheduled to be released in late spring/early summer 2022 (See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>). Furthermore, we finalized in the 2020 RADV Amendments Rule (85 FR 77002-77005) that 2019 and 2020 error rates for non-exiting issuers will be averaged together at the issuer level and will be applied to 2020 risk adjustment transfers. Positive error rate exiting issuer HHS-RADV adjustments for the 2019 and 2020 benefit years will continue to be applied separately to the risk scores and transfers for the respective benefit year being audited.

noted the overlap in timelines, but did not see the need to account for 2017 and 2018 HHS-RADV adjustments differently than was proposed.

Finally, we received a few comments requesting that we retain the allowance in the URRT for states to determine whether an adjustment for HHS-RADV in the URRT would be reasonable and justifiable in any particular benefit year.

Response: After considering all comments on the proposed updated timeline, we are finalizing the changes to the timeline for collection and disbursement of HHS-RADV results as proposed, beginning with the 2019 benefit year of HHS-RADV.¹⁶⁴ In response to comments concerning the transition period between the current HHS-RADV timeline (applicable for the 2017 and 2018 benefit years) and the timeline finalized in this rule (applicable beginning with the 2019 benefit year), we considered whether accommodations would be needed during the transition period as we recognize that the transition years will result in 2 years of HHS-RADV being reported during one MLR reporting period.

This included consideration of the options from the commenter suggesting that 2017 HHS-RADV be reported in 2020 MLR filings and 2018 HHS-RADV adjustments be reported in 2021 filings. However, we did not propose and are not making any changes with respect to the timeline for collection and disbursement of HHS-RADV results for the 2017 or 2018 benefit year of HHS-RADV. We also do not believe these alternative options would appropriately address 2017 and 2018 HHS-RADV for MLR reporting purposes. First, the current timeline for 2017 and 2018 HHS-RADV were established in notice-and-comment rulemaking,¹⁶⁵ and as such, issuers have expected and are preparing to report these amounts on their 2021 and 2022 MLR reports, respectively, since the finalization of the 2020 Payment Notice. Second, we note that the suggested option would require that 2018 HHS-RADV be reported alongside the combined results for 2019 and 2020 RADV, which would create – rather than eliminate or mitigate – the

¹⁶⁴ Ibid.

¹⁶⁵ 84 FR 17454 at 17506-17507.

same concerns the commenter was trying to address through their alternative suggestions. The alternative would just shift the overlap to a different MLR reporting year. We further note this type of overlap during a transition period is a natural result of implementing this type of policy change.

As outlined elsewhere in this rule and in the proposed rule, after further consideration of stakeholder concerns regarding the timeline established in the 2020 Payment Notice, we proposed and are finalizing the proposed update to revert to the prior schedule for collection and disbursement of HHS-RADV results beginning with the 2019 benefit year. This update responds to stakeholder concerns about the potential conflicts with certain state accounting requirements and the potential negative impact on certain issuers' MLR rebate position. It also aligns with other recently finalized changes to HHS-RADV program requirements. We intend to monitor implementation of the collection and disbursement of HHS-RADV payments and charges, including feedback on lessons learned from stakeholders, and will consider whether further guidance or consideration of these issues is warranted.

To assist stakeholders in understanding the MLR reporting period associated with each benefit year of risk adjustment and HHS-RADV, incorporating the updated timeline that is finalized in this rule, we have created the following table that explains which benefit years of risk adjustment and HHS-RADV adjustments should be reported in which MLR reporting years for the 2020 – 2025 MLR Reporting Years:

TABLE 9: Risk Adjustment and HHS-RADV Benefit Years to Include in MLR Reports for MLR Reporting Years 2020-2025

MLR Reporting Year	RA Benefit Year to Include	RADV Benefit Year(s) to Include
2020 (Filed in 2021)	2020	NA
2021 (Filed in 2022)	2021	2017
		2019 & 2020 *, **
2022 (Filed in 2023)	2022	2018
		2021*
2023 (Filed in 2024)	2023	2022
2024 (Filed in 2025)	2024	2023
2025 (Filed in 2026)	2025	2024

* Including multiple years of HHS-RADV due to transition to the policy finalized in this rule to revert to the prior schedule for collection and disbursement of HHS-RADV results beginning with the 2019 benefit year.

** See 2020 HHS-RADV Amendments Rule, where we finalized a transition from the prospective application of HHS-RADV adjustments. [The exception to the prospective application of HHS-RADV adjustments is for exiting issuers, whose HHS-RADV results are currently used to adjust risk scores and transfers for the benefit year being audited (rather than the following benefit year's transfers). See 83 FR 16965 – 66 and 84 FR 17503 – 04.]

Finally, we disagree with commenters who suggest retaining portions of the URRT instructions pertaining to reporting HHS-RADV adjustments that allowed states the option to allow issuers to take into consideration the impact of HHS-RADV from another benefit year in rating for the upcoming benefit year. Without the 2-year delay between the release of HHS-RADV results and the collections of HHS-RADV adjustments, we are concerned that the continued inclusion of these instructions would be confusing. Further, there is no longer a connection between the collection and disbursement of HHS-RADV adjustments and the applicable upcoming benefit year to support continuing to provide the flexibility in the URRT instructions. We intend to monitor implementation of the collection and disbursement of HHS-RADV payments and charges and will consider whether further guidance is needed.

e. Second Validation Audit and Error Rate Discrepancy Reporting Windows

Under § 153.630(d)(2), issuers have 30 calendar days to confirm the findings of the SVA (if applicable) 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. As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and SVA receive

SVA findings.¹⁶⁶ We proposed to amend paragraph (d)(2) to shorten the window to confirm the findings of the SVA (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 2020 benefit year HHS-RADV. The proposed shorter discrepancy reporting timeframes were intended to ensure that we can resolve as many issues as possible in advance of publication of the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year. Based on the first 2 payment years of HHS-RADV, we explained that HHS believes that this shortened window would not be overly burdensome to issuers, and that any disadvantages of this shortened window would be outweighed by the benefits of timely resolution of as many discrepancies as possible prior to the release of the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year. We further noted that a 15 calendar day discrepancy reporting window is consistent with the IVA sample and EDGE discrepancy reporting windows at §§ 153.630(d)(1) and 153.710(d), respectively. We proposed shortening the discrepancy window in the 2020 Payment Notice, but did not finalize the proposal in response to comments suggesting that we revisit this proposal once we had completed a payment year of HHS-RADV.

We are not finalizing the proposal to shorten the discrepancy reporting windows under § 153.630(d)(2) for issuers to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy report to dispute the foregoing from 30 to 15 calendar days and will instead maintain the existing 30 calendar day discrepancy reporting windows.

We received public comments on the proposed updates to the SVA and error rate discrepancy reporting windows. The following is a summary of the comments we received and our responses.

¹⁶⁶ 84 FR 17495.

Comment: Commenters were opposed to the proposal to shorten the SVA and risk score error rate attestation and discrepancy reporting timeframe from 30 to 15 days and instead recommended maintaining the existing 30 calendar day reporting window. Several commenters stated that they believed that the proposed 15-day timeline would not provide adequate time for issuers to complete a thorough review of the SVA findings or the calculation of the risk score error rate. Another commenter suggested that the timeframes could be shortened elsewhere in the HHS-RADV process in order to keep the 30-day reporting timeframes, noting that it would be helpful for issuers to receive their HHS-RADV error rates sooner for use in pricing.

Response: After consideration of the comments received, we are not finalizing the proposal to shorten the attestation and discrepancy reporting window under § 153.630(d)(2) from 30 to 15 calendar days and will instead maintain the existing 30 day attestation and discrepancy reporting window. Issuers will continue to have 30 calendar days to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy report.

As a result of these comments, we are not finalizing the proposal to shorten the SVA and risk score error rate attestation and discrepancy reporting timeframes from 30 calendar days to 15 calendar days.

8. Risk Adjustment Data Reporting Requirements for Future Premium Credits (§ 153.710)

As detailed earlier in this preamble, on September 2, 2020, we issued an interim final rule (IFR) on COVID-19 wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year to align with the relaxed enforcement policy announced in guidance.¹⁶⁷ For the 2021 benefit year and beyond, we proposed to permanently adopt these risk adjustment reporting requirements for all health insurance issuers in the individual and small group markets who elect to offer premium credits

¹⁶⁷ See, for example, “Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency,” August 4, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

during a public health emergency declared by the Secretary of HHS (declared PHE)¹⁶⁸ if the premium credits are permitted by HHS in future benefit years. Specifically, we proposed that issuers of risk adjustment covered plans that provide temporary premium credits during a declared PHE when permitted by HHS in future benefit years must report to their EDGE servers adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums. In the proposed rule, we also proposed to clarify that HHS's calculation of risk adjustment payment and charges for the 2021 benefit year and beyond under the state payment transfer formula would be calculated using the statewide average premium reflecting actual premiums billed, which takes into account any temporary premium credits provided as a reduction in premium for the applicable months of coverage during a declared PHE when permitted by HHS in future benefit years.¹⁶⁹

As noted in the September 2020 IFR on COVID-19, we believe that these requirements are necessary and appropriate because if HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur that financially impact individual issuers. For example, absent the requirement that issuers offering premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-than-average risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that

¹⁶⁸ The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: (a) a disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

¹⁶⁹ As noted above, we are finalizing this clarification and will calculate transfers under the state payment transfer for the 2021 benefit year and beyond using the statewide average premium, reflecting actual premiums billed, taking into account any temporary premium credits provided during a declared PHE when permitted by HHS.

reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool.

Therefore, we believe that requiring issuers that offer temporary premium credits during a declared PHE, when permitted by HHS, to accurately report to the EDGE server the adjusted, lower premium amounts actually billed to enrollees is most consistent with existing risk adjustment program requirements and mitigates the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts billed to enrollees, while not imposing additional financial burdens on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts. We requested comment on this proposal. We are finalizing this policy as proposed. Issuers of risk adjustment covered plans that provide temporary premium credits when permitted by HHS in the 2021 benefit year and beyond during a declared PHE must report to their EDGE servers adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums for the applicable months of coverage.

We received public comments on the proposals related to risk adjustment data reporting requirements for future premium credits (§ 153.710) and the accompanying proposed policies related to the calculation of plan average premium and state average premium requirements for extending future premium credits (§ 153.320). The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported the policies related to the adoption of the flexibility to allow issuers to grant temporary premium credits to beneficiaries should a future PHE be declared as this supports beneficiary access to care. One commenter expressed concern that allowing plans to change their premiums with knowledge of their competitors' premiums in the state market risk pool gives them an unfair advantage in risk adjustment. This commenter was concerned that a plan that initially offered too high a premium

relative to its risk could offer a premium reduction to lower its risk adjustment payout after knowing its competitors pricing structure.

Response: We believe that it is important to require issuers that choose to offer temporary premium credits during a declared PHE to report the actual reduced amount of premium billed to enrollees in the state market risk pool. If HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur that financially impact other issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-than-average risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium billed to enrollees by the issuer in the state market risk pool. Therefore, the finalized approach is most consistent with existing risk adjustment program requirements and mitigates the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts billed to enrollees, while not imposing additional financial burdens on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts.

We also note that this proposal does not seek to extend or expand issuer ability to offer temporary premium credits. Rather, we proposed to permanently adopt policies to guide risk adjustment calculations and reporting if issuers of risk adjustment covered plans elect to offer premium credits during a declared PHE when permitted by HHS in future benefit years. By limiting this policy to future declared PHEs, the potential creation of incentives for issuers to adjust premiums with knowledge of their competitors' premiums in an attempt to achieve a more favorable risk adjustment transfer (that is, a higher payment or lower charge) is limited. Further,

we believe the benefits associated with encouraging issuers to provide temporary premium credits to help consumers maintain continuous health coverage during a declared PHE outweigh these potential risks and is an appropriate approach to balancing the different equities involved during declared PHEs.

Comment: A few commenters expressed concern as to how small group market plans will be able submit the actual premium amount billed to plan enrollees through EDGE data, as small group market premium reporting is completed at a subscriber level. These commenters requested that HHS clarify the intended approach for issuers facing this operational challenge.

Response: We understand the importance of clarifying this process for all issuers in the individual and small group markets (including merged markets) who offer temporary premium credits during a declared PHE, when permitted by HHS for future benefit years, may fulfill the data reporting requirements to offer premium credits during a declared PHE if the premium credits are permitted by HHS in future benefit years. Issuers of small group plans should apply the premium credit or discount provided in the small group market uniformly to all enrollees in the policy eligible for the credit for the applicable month, ensuring that the aggregate premium reflected in their internal system and EDGE is the lower, reduced amount for that month, including any premium changes that result from retro-active enrollment changes. If these premium credits are permitted in the 2021 benefit year or beyond, we intend to continue to work closely with issuers to implement this policy and will consider whether further guidance is warranted.

Comment: Several commenters supported the proposed approach to use the actual premium amount billed to enrollees, reflective of permitted temporary premium credits, when calculating the plan average premium and statewide average premium for their application in the risk adjustment program. A few of these commenters also mentioned that they supported our proposal to follow this approach when calculating the plan average premium and state average premium calculation in states with approved state flexibility requests under § 153.320(d).

Response: We appreciate these comments and agree with commenters. We are finalizing this policy as proposed. This policy ensures that the plan average premium and statewide average premium used in the state payment transfer formula is calculated using the actual premiums billed to plan enrollees, and also applies this methodology to the calculation of transfers under the state payment transfer formula in states that receive approval for a request to reduce transfers under § 153.320(d).

After consideration of comments on these proposals, we are finalizing as proposed the policy to permanently adopt these risk adjustment reporting requirements for the 2021 benefit year and beyond, for all issuers of risk adjustment covered plans who elect to offer premium credits during a PHE declared by the Secretary of HHS (declared PHE) if the premium credits are permitted by HHS in future benefit years. We are also finalizing, as proposed, the permanent adoption of the accompanying policy for HHS to calculate the plan average premium and statewide average premium under the state payment transfer formula using issuers' adjusted premium amounts, reflective of temporary premium credits provided by issuers during a declared PHE when such credits are permitted by HHS. That is, the lower actual premiums for which plan enrollees would be responsible would be the amounts used in the calculations under the state payment transfer formula to reflect these temporary premium credits. This approach will also extend to calculations under the state payment transfer formula in states that receive approval for a request to reduce transfers under § 153.320(d).

D. Part 155 – Exchange Establishment Standards and Other Related Standards under the Affordable Care Act

1. Definitions (§ 155.20)

a. Definitions of QHP Issuer Direct Enrollment Technology Provider and Agent or Broker
Direct Enrollment Technology Provider

We proposed to amend § 155.20 to add a definition of QHP issuer direct enrollment technology provider, which we proposed to mean a business entity that provides technology

services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230. We also proposed that this definition of QHP issuer direct enrollment technology provider explicitly acknowledge that a web-broker may also provide services to QHP issuers as a QHP issuer direct enrollment technology provider to clarify that being a web-broker does not preclude that entity from providing technology services or an information technology platform to QHP issuers to facilitate QHP issuers' participation in direct enrollment. In addition, we proposed to modify the current definition of direct enrollment technology provider in § 155.20 to distinguish it from the new proposed definition of QHP issuer direct enrollment technology provider by renaming the term agent or broker direct enrollment technology provider. We proposed these new and modified definitions to capture the full array of potential arrangements between technology companies and entities seeking to use the direct enrollment pathways to facilitate enrollments in QHPs offered in an FFE or SBE-FP in a manner that constitutes enrollment in the Exchange. To align with these proposed new and modified definitions, we further proposed to modify the definition of web-broker to replace the last sentence, which stated that the term includes a direct enrollment technology provider, to instead indicate that the term web-broker includes an agent or broker direct enrollment technology provider.

In the 2020 Payment Notice final rule, we amended § 155.20 to define “direct enrollment technology provider” to mean “a type of web-broker business entity that is not a licensed agent, broker, or producer under [s]tate 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.”¹⁷⁰ This definition captures instances in which 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,

¹⁷⁰ See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters; Final rule, 84 FR 17454 at 17562 (April 25, 2019).

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, the current framework establishes that these technology companies are a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless indicated otherwise.¹⁷¹

As the FFE direct enrollment program has evolved, particularly with the introduction and increased utilization of the enhanced direct enrollment (EDE) pathway, the technical requirements and expertise needed to participate in direct enrollment have become substantially more complex. As a result, technology companies are increasingly relied upon to develop, host, manage, and customize the technical platforms that underpin direct enrollment entity non-Exchange websites. Technology companies have emerged to support the participation of QHP issuers in direct enrollment, as well as agents, brokers, and web-brokers. In the context of EDE, some of these technology companies build technical platforms prior to finalizing contractual relationships with agents, brokers, web-brokers, or QHP issuers and some of these technology companies provide platforms that are used to host direct enrollment websites for both QHP issuers and agents, brokers, or web-brokers. Under the current framework, the technology company is itself a web-broker and often provides direct enrollment services under its own branding while also wanting to offer its technology platform and accompanying services to other agents, brokers, web-brokers, or QHP issuers to facilitate their respective participation in direct enrollment. As part of the services it provides as a technology company, it may offer customized direct enrollment websites that leverage its technical platform to other entities that allows for additional systems or functionality or the use of the other entity's branding. Because the current regulatory definition does not include a reference to QHP issuers, questions have arisen

¹⁷¹ For example, § 155.220(d)(2) exempts direct enrollment technology providers from the training requirement that is part of the annual FFE registration process for agents and brokers.

regarding the ability and accompanying requirements for QHP issuers to engage such entities to assist with the development and hosting of a non-Exchange website to facilitate the QHP issuer's participation in direct enrollment. For these reasons we proposed to create a new definition of QHP issuer direct enrollment technology provider and update the definitions of direct enrollment technology provider and web-broker as described above, to clarify that QHP issuers can also engage the services of these technology companies and better align with the evolving business models of entities involved in the FFE direct enrollment program. We also proposed to include language in the new definition of QHP issuer direct enrollment technology provider to clarify that when such entities partner with QHP issuers, they are downstream or delegated entities of the QHP issuer. This is similar to the approach adopted in § 155.221(e) for third-party auditors hired by QHP issuers or web-brokers to perform operational readiness audits. By including this language, we intended to clarify and ensure that these QHP issuer direct enrollment technology providers would be subject to HHS oversight as the delegated or downstream entity of the QHP issuer, and the QHP issuer would be responsible for compliance with all applicable requirements. This approach was also intended to clarify that when providing its technology services and support, or providing access to an information technology platform, to a QHP issuer, QHP issuer direct enrollment technology providers would be subject to the rules applicable to the QHP issuer with whom they are partnering to the extent they are performing activities on behalf of the QHP issuer implicating those rules. For example, if a QHP issuer direct enrollment technology provider is assisting with the development of a non-Exchange website for a QHP issuer, the QHP issuer display requirements captured at § 156.1230(a)(1)(ii) would apply.

We sought comment on this proposal.

We did not receive public comments on the proposal to update the definition of web-broker, and are finalizing that proposal as proposed. We received public comments on the proposed addition of a definition of QHP issuer direct enrollment technology provider and

updates to the definition of direct enrollment technology provider. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to define QHP issuer direct enrollment technology provider and agent or broker direct enrollment technology provider. One commenter noted that technology providers play an important role in shaping the experience of consumers and supported making regulations more clearly applicable to them. Another commenter supported the proposed definitions, but requested clarification that a single entity could serve as both types of technology provider and as a web-broker.

Response: We appreciate the comments in support of this proposal and are finalizing the proposal as proposed. To clarify, a single entity may serve as a QHP issuer direct enrollment technology provider, an agent or broker direct enrollment technology provider, and as a web-broker. However, we note that an entity that functions in multiple capacities must comply with the applicable rules for the context in which they are operating. For example, if a web-broker is hosting a direct enrollment website for a QHP issuer and therefore is operating as a QHP issuer direct enrollment technology provider, the QHP issuer display requirements captured at § 156.1230(a)(1)(ii) would apply to the website the web-broker is hosting on behalf of the QHP issuer while the web-broker display requirements in § 155.220 would remain applicable to the website the web-broker is hosting with its own branding.

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

To continue our efforts to standardize regulatory references to web-brokers, we proposed to replace all references in § 155.205(c) to “an agent or broker subject to § 155.220(c)(3)(i)” with the term “web-broker.” In the 2020 Payment Notice final rule, we amended § 155.20 to define the term “web-broker”¹⁷² to mean an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, that is registered with an Exchange under § 155.220(d)(1) and develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers

¹⁷² See 84 FR 17563.

with the selection of and enrollment in QHPs offered through the Exchange (a process referred to as direct enrollment). We also amended §§ 155.220 and 155.221 to incorporate the term web-broker as newly defined, where applicable. However, at the time, we overlooked the fact that § 155.205(c) also contains several of these general references to agents and brokers subject to § 155.220(c)(3)(i) that should have been updated as part of this earlier effort to use the term web-broker as newly defined. Such references appear in § 155.205 paragraphs (c)(2)(i)(B), (c)(2)(iii)(B), (c)(2)(iv) introductory text, and (c)(2)(iv)(C). To avoid confusion and correct this oversight, we proposed to standardize regulatory references to web-brokers by replacing all references in § 155.205(c) to “an agent or broker subject to § 155.220(c)(3)(i)” with the term “web-broker.” We sought comment on this proposal.

In addition, we proposed to revise a requirement related to website content translations for QHP issuers and web-brokers participating in the FFE EDE program that are subject to §§ 155.205(c)(2)(iv)(B) and 155.205(c)(2)(iv)(C) respectively. Currently under §§ 155.205(c)(2)(iv)(B) and (C), QHP issuers and web-brokers are required to translate website content into any non-English language that is spoken by a limited English proficient (LEP) population that makes up 10 percent or more of the total population of the relevant state. Web-brokers are currently required to translate website content within 1 year of registering with the Exchange, while QHP issuers are currently required to translate website content beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year.

In the proposed rule, we proposed to allow QHP issuers and web-brokers participating in the FFE EDE program additional time to come into compliance with the website content translation requirements. Specifically, we proposed that a QHP issuer or web-broker participating in the FFE EDE program would have 12 months from the date the QHP issuer or web-broker begins operating its FFE-approved EDE website in the relevant state to comply with website content translation requirements under §§ 155.205(c)(2)(iv)(B) and (C) for website content added to their websites as a condition of participation in the FFE EDE program. We

noted this proposed flexibility would not absolve QHP issuers and web-brokers from complying with website content translation requirements under paragraphs (c)(2)(iv)(B) and (C) that are unrelated to their participation in the FFE EDE program within the applicable timeframes.¹⁷³

We sought comment on whether this proposed flexibility for QHP issuers and web-brokers participating in the FFE EDE program in relevant states would have impacted accessibility to Exchange coverage for LEP communities, or otherwise would have negatively impacted the operation of and consumer access to Exchanges. In addition, we sought comment from QHP issuers and web-brokers as to whether this proposed change would have fostered investment in states where there is a significant LEP community and provide additional incentives for such entities to expand into relevant states. Lastly, we sought comment from assisters about any impacts this proposed change would have had on their proposed ability to work with web-brokers and use EDE websites as described in the proposed rule (and below) when assisting members of the LEP community with Exchange enrollment.

We did not receive public comments on the proposal to replace all references in § 155.205(c) to “an agent or broker subject to § 155.220(c)(3)(i)” with the term “web-broker.” We are finalizing that proposal as proposed. We did receive public comments on the proposal to provide additional time to entities participating in EDE to translate website content added to their websites as a condition of participation in the FFE EDE program. The following is a summary of the comments we received and our responses.

Comment: The vast majority of comments received opposed finalizing the proposal to provide EDE entities up to 12 months to translate EDE-specific website content. Generally, commenters expressed concerns about possible conflicts between the proposal and statutory non-discrimination requirements or asserted that the proposal would create or exacerbate racial or

¹⁷³ See also “Guidance and Population Data for Exchange, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and §156.250,” March 30, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf>.

ethnic disparities. Some commenters stated that allowing EDE entities to delay the translation of their website content could deprive LEP populations of meaningful access in violation of the non-discrimination provisions in Section 1557 of the ACA. One commenter pointed out this could allow an EDE entity to go through an entire open enrollment period without translating its website content, potentially leaving significant numbers of LEP consumers without information in their languages. The same commenter acknowledged the significant resources involved in developing an EDE website, but did not believe it should take 12 more months to have it translated. Another commenter stated this proposal would limit coverage received by LEP populations, creating racial and ethnic disparities that raise serious concerns under both the ACA and broader federal civil rights laws. Another commenter stated the existing translation requirements are already inadequate and should not be weakened at the expense of LEP consumers. Two commenters supported the proposal. One stated the proposed rule struck an appropriate balance between affording EDE entities additional implementation flexibility and maintaining the language accessibility standards.

Response: While we appreciate the comments in support of this proposal, we are not finalizing this proposal given the concerns expressed by the majority of commenters, and the fact that no QHP issuers or web-brokers (small or otherwise) commented to specifically indicate this proposal would incentivize their participation in states where there is a significant LEP population and where translation of their websites would have eventually been required. Almost all commenters stated that this proposal could reduce access to coverage for LEP populations, create further health inequities among this population, or possibly violate statutory non-discrimination requirements. We acknowledge these concerns are worth careful consideration and outweigh any argument to finalize this proposal at this time.

3. Navigator Program Standards (§ 155.210)

Sections 1311(d)(4)(K) and 1311(i) of the ACA require the Secretary to establish a Navigator program under which HHS 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 APTC and CSRs, and 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, in collaboration with states, to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. We have implemented the statutorily required Navigator duties through regulations at §§ 155.210 (for all Exchanges) and 155.215 (for Navigators in FFEs). Certified Application Counselors (CACs) duties have been implemented through regulations at § 155.225.

We proposed allowing, but not requiring, Navigators and CACs in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent permitted by state law. For a discussion of the proposal to allow Navigators and CACs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment, along with a summary of comments received and our responses to these comments, please see the preamble to § 155.220.

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

a. Navigator and Certified Application Counselor Use of Web-broker Websites

In the 2020 Payment Notice, we proposed, but did not finalize, a modification of our policy that prohibits Navigators and CACs (together referred to here as “assisters”) from using

web-broker websites to assist with QHP selection and enrollment.¹⁷⁴ At the time, adoption of EDE functionality by web-brokers was still limited, and we decided to focus on the implementation and oversight of the EDE pathway before revisiting the current policy regarding assister use of web-broker websites. Since then, EDE functionality has become more user-friendly and increasingly more consumers are using the EDE pathway to enroll in Exchange coverage.

In the proposed rule, we proposed permitting but not requiring, assisters in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided the non-Exchange website met certain conditions. We proposed to provide states with a State Exchange that does not rely on HealthCare.gov the discretion to permit their assisters to use web-broker non-Exchange websites.

We proposed several amendments to § 155.220 to capture this flexibility for assisters in FFE and SBE-FP states to use web-broker non-Exchange websites to assist consumers and sought comment on all of these proposals.

We received public comments on the proposal to allow, but not require, Navigators and CACs in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent permitted by state law. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters opposed the proposal to allow assisters to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment. Commenters were concerned about whether assisters could remain fair and impartial if they were assisting consumers using web-broker non-Exchange 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

¹⁷⁴ See 84 FR 17515 through 17521.

consumers may encounter when using web-broker non-Exchange websites that include marketing for non-QHP products. Several commenters also expressed concerns regarding the cost of providing adequate training to assisters to understand multiple platforms for enrollment. They noted that this may take critical time away from assisters serving consumers. Many commenters expressed concern that assister use of web-broker non-Exchange websites to assist with QHP selection and enrollment would reduce or not facilitate enrollment in Medicaid and CHIP. Also, many commenters suggested that CMS invest resources to improve and expand the functionality of HealthCare.gov and expand assister programs instead of dedicating resources to implement this proposal.

Response: After consideration of the comments received in response to this proposal, we agree with the commenters that there are concerns related to assister use of web-broker non-Exchange websites to assist with QHP selection and enrollment that warrant further consideration. Therefore, we are not finalizing the proposed modification to the current policy that prohibits assisters from using web-broker non-Exchange websites to assist with QHP selection and enrollment or the accompanying proposals to amend and replace § 155.220(c)(3)(i)(D). The current policy, which prohibits the use of web-broker non-Exchange websites by assisters to assist with QHP selection and enrollment, remains in effect.

b. QHP Information Display on Web-broker Websites

We proposed to provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for QHPs in certain circumstances. Currently, § 155.220(c)(3)(i)(A) requires that a web-broker non-Exchange website must 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). To the extent that not all information required under § 155.205(b)(1) is displayed on the web-broker's website for a QHP, the web-broker's website must 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 link to the Exchange website. The preamble in the proposed and final rules that established the current text in § 155.220(c)(3)(i)(A) explained the intent of this requirement was that a web-broker website must display all information required under § 155.205(b)(1) unless the information was not available to the web-broker, in which case the web-broker website must display the standardized disclaimer.¹⁷⁵ Section 155.220(c)(3)(i)(D) similarly currently requires web-brokers to display all QHP data provided by an Exchange on its non-Exchange website used to participate in the FFE direct enrollment program (whether Classic DE or EDE). In the early years of Exchange operations, we released a data file with limited QHP details (the QHP limited file) that provided web-brokers with a basic set of QHP data that could be used to satisfy the display requirements. Display of the data elements from the QHP limited file data, in combination with a standardized disclaimer (the plan detail disclaimer), became the *de facto* minimum required to satisfy the web-broker's obligation to display QHP information on its non-Exchange website. In adopting this approach, we recognized that the Exchange may not have been able to provide web-brokers with certain data elements necessary to meet the § 155.205(b)(1) requirements, such as premium information, due to confidentiality requirements, web-broker appointments with QHP issuers, and state law. We also recognized some of the data elements, such as quality rating information, were not going to be available in the initial years of the Exchanges' operation.¹⁷⁶

In new proposed § 155.220(n), we proposed to establish an exception to the web-broker display requirements captured at paragraphs (c)(3)(i)(A) and (D). We proposed to revise paragraph (c)(3)(i)(A) to require a web-broker non-Exchange website to 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), except as permitted under § 155.220(n). We proposed a similar revision to § 155.220(c)(3)(i)(D). At new proposed paragraph (n), we proposed certain

¹⁷⁵ See 78 FR at 37046 and 78 FR at 54077.

¹⁷⁶ See Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54069 at 54077 (August 30, 2013).

flexibilities regarding display of QHP information if a web-broker's non-Exchange website does not support enrollment in a QHP, except in cases where the web-broker's website is intended to be available for use by assisters consistent with proposed paragraph (c)(3)(iii)(A). In that case, the flexibility at new proposed paragraph (n) would not be available. A web-broker's non-Exchange website may not support enrollment in a QHP if the web-broker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances, we proposed that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, web-brokers would be required to display the following limited, minimum information for such QHPs: issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information. To take advantage of this new proposed flexibility, we also proposed that the web-broker's non-Exchange website would be required to identify to consumers the QHPs, if any, for which the web-broker's website does not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange website, and includes a link to the Exchange website. We noted that we believed this proposal struck an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. It also would minimize burdens for web-brokers by not requiring them to build functionality and processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for which they do not have an appointment to sell.

To more closely align the plan detail disclaimer text¹⁷⁷ with the intent of this proposal, we noted that we planned to issue further guidance revising the text of the disclaimer so that it can be clearly associated with any QHPs for which the web-broker website does not facilitate enrollment. For example, the current disclaimer text states, in relevant part, the web-broker “isn’t able to display all required plan information about this Qualified Health Plan at this time.” We noted that we were considering modifying this text so that it states, in relevant part, the web-broker “doesn’t display all plan information about, and doesn’t facilitate enrollment in, this Qualified Health Plan at this time.”

We invited comments on the proposed required limited, minimum QHP details that must be displayed for those QHPs that the web-broker does not facilitate enrollment in through its non-Exchange website and the proposed edits to the plan detail disclaimer text. We also sought comment on whether to require display of any additional elements identified under § 155.205(b)(1) among the limited, minimum information, such as summaries of benefits and coverage.¹⁷⁸

We received public comments on the proposed updates to requirements regarding QHP information display on web-broker non-Exchange websites. The following is a summary of the comments we received and our responses.

Comment: Almost all commenters advocated for requiring that web-broker non-Exchange websites display more QHP information than the proposed rule proposed to require, even in cases when the web-broker non-Exchange website does not support enrollment in a QHP. The vast majority of commenters either advocated for requiring web-broker non-Exchange

¹⁷⁷ The current plan detail disclaimer states: “[Name of Company] isn’t able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at HealthCare.gov.” See also Section 5.3.2 of the “Federally-Facilitated Exchanges (FfEs) and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual.” Available at https://www.regtap.info/uploads/library/ENR_FFEFFSHOPENrollmentManual2020_5CR_090220.pdf.

¹⁷⁸ Section 155.205(b)(1) references the following comparative QHP information: premium and cost-sharing information, the summary of benefits and coverage, metal level, results of enrollee satisfaction surveys, quality ratings, medical loss ratio information, transparency of coverage measures, and the provider directory.

websites to display all available QHP information for all available QHPs, or generally supported making it easier for consumers to obtain comparative information for all available QHPs when consumers are using web-broker non-Exchange websites. One commenter acknowledged that the proposal (including the proposed updates to the plan detail disclaimer) represented a significant improvement over the status quo and would allow consumers to make more educated comparisons between QHPs when using web-broker non-Exchange websites, but still expressed a preference for requiring that all information for all available QHPs be displayed. Another commenter stated that the “no wrong door” intent of the ACA would be best met by requiring the display of all available QHP information for all available QHPs on web-broker non-Exchange websites. Another commenter asserted that there is no consumer-oriented rationale for web-broker non-Exchange websites to display limited QHP information now that there is access to APIs that provide the information. One commenter specifically noted that the proposal did not require display of summaries of benefits and coverage and quality information when a web-broker non-Exchange website does not support enrollment in a particular QHP, and that that information is critical for consumers to evaluate and compare QHP options. Two commenters supported the proposal as proposed.

Response: After consideration of the comments received, we are not finalizing the proposed amendments to § 155.220(c)(3)(i)(A), (c)(3)(i)(D), or (n). We agree that the display of more QHP information on web-broker non-Exchange websites is in the best interest of consumers to aid them in comparing QHP options without having to potentially navigate to multiple websites, and understand why the majority of commenters advocated for web-broker non-Exchange websites displaying all of the comparative information listed in § 155.205(b)(1), including summaries of benefits and coverage and quality information. We also believe requiring web-broker non-Exchange websites to display additional QHP information is reasonable given that QHP information has been more readily accessible for some time, both through public use files and the Marketplace API. In addition, we note that the specific suggestions made by

commenters regarding some of the QHP information that should be displayed on web-broker non-Exchange websites (that is, summaries of benefits and coverage and quality information) are part of the QHP information display requirements in § 155.220(c)(3)(i)(A) through its cross-reference to § 155.205(b)(1).¹⁷⁹

Thus, we intend to further consider these issues and clarify the display requirements for web-broker non-Exchange websites in future rulemaking. In the interim, we also intend to limit our current use of enforcement discretion that permits web-brokers to only display issuer marketing name, plan marketing name, plan type, and metal level for all available QHPs,¹⁸⁰ so that web-broker non-Exchange websites will be required to display all QHP information consistent with § 155.205(b)(1) and (c), with the exception of medical loss ratio information and transparency of coverage measures under § 155.205(b)(1)(vi) and (vii), for all available QHPs. As such, until these issues are addressed in future rulemaking, beginning at the start of the open enrollment period for plan year 2022, web-broker non-Exchange websites will be required to display all QHP information received from the Exchange or directly from QHP issuers, consistent with the requirements of § 155.205(b)(1) and (c).¹⁸¹ During this time, we will exercise enforcement discretion and not deem a web-broker non-Exchange website out of compliance with § 155.220(c)(3)(i)(A) and (D) with respect to the display of medical loss ratio information and transparency of coverage measures if the web-broker non-Exchange website displays the other required standardized comparative information consistent with § 155.205(b)(1) and (c). Prior to the start of the open enrollment period for plan year 2022, if a web-broker's non-Exchange website does not display all QHP information consistent with the requirements of § 155.205(b)(1) and (c), other than medical loss ratio information and transparency of coverage measures, it must prominently display the standardized disclaimer provided by HHS and provide

¹⁷⁹ See 45 CFR 155.205(b)(1)(ii), (iv), and (v).

¹⁸⁰ "Processes and Guidelines for Becoming a Web-broker in the Federally-facilitated Exchanges: An Overview for New and Existing Web-brokers," October 2017, available at <https://www.cms.gov/files/document/processes-becoming-web-broker.pdf>.

¹⁸¹ HHS makes QHP information available, including the standardized comparative information under § 155.205(b)(1)(i) – (v) and (viii), through public use files and the Marketplace API.

a link to the Exchange website. We note that this interim approach applicable beginning with the start of the plan year 2022 open enrollment period does not establish new requirements and instead represents a change in the exercise of enforcement discretion regarding the standardized comparative information web-brokers are required to display under existing regulations following our consideration of comments on the proposed changes to the web-broker QHP display requirements.¹⁸² We intend to continue our collaborative approach of working with web-broker and other enrollment partners to ensure consumers have information to make informed coverage choices while balancing the burdens and costs imposed on our partners.

c. Web-broker Operational Readiness Review Requirements

We proposed amendments to further clarify the operational readiness requirements applicable to web-brokers by adding a new proposed § 155.220(c)(6). In the 2018 Payment Notice final rule, we adopted rules to require web-brokers to demonstrate operational readiness, including compliance with applicable privacy and security requirements, prior to participating in the FFE direct enrollment program.¹⁸³ Our intent in codifying this requirement was to build on the onboarding and testing processes for a web-broker to be approved to use the direct enrollment pathways. We noted the expectation that additional operational readiness requirements would be established specific to EDE to account for the additional functionality associated with that pathway.¹⁸⁴ At the same time, we established similar requirements for QHP issuers to demonstrate operational readiness and compliance with applicable requirements prior to their use of the direct enrollment pathway.¹⁸⁵ In the 2020 Payment Notice final rule, we consolidated these similar requirements from their prior locations at §§ 155.220(c)(3)(i)(K) and 156.1230(b)(2) into § 155.221(b)(4) as part of our effort to streamline requirements applicable to all direct enrollment entities.¹⁸⁶ In the proposed rule, we proposed to create a new

¹⁸² See 45 CFR 155.220(c)(3)(i)(A) and (D).

¹⁸³ See 81 FR 94176.

¹⁸⁴ See 81 FR 94120.

¹⁸⁵ See 81 FR 94152.

¹⁸⁶ See 84 FR 17524.

§ 155.220(c)(6) to capture operational readiness requirements applicable to web-brokers that host non-Exchange websites to complete QHP selection or the Exchange eligibility application. In proposed paragraph (c)(6), we proposed to include introductory language that reflects the requirement for a web-broker to demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in a form and manner specified by HHS, of certain information or testing processes. As reflected in proposed paragraphs (c)(6)(i) through (v), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes may include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers would have to maintain and provide access to testing environments that reflect their prospective or actual production environments. We proposed these amendments to codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.¹⁸⁷ We did not propose to extend the same requirements to QHP issuers participating in

¹⁸⁷ See, for example, "Updated Web-broker Direct Enrollment Program Participation Minimum Requirements," May 21, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf>.

the FFE direct enrollment program, because QHP issuers, as HIPAA-covered entities, are subject to longstanding federal requirements and oversight related to the protection of PII and PHI that are not necessarily applicable to web-brokers. With HIPAA privacy and security regulations and oversight in place and applicable to QHP issuers, HHS has adopted a risk acceptance approach for QHP issuers allowing them to participate in the FFE direct enrollment program, in some cases, without imposing certain requirements that are in place for web-brokers. In addition, QHP issuers are subject to more extensive oversight by state regulators than web-brokers.

We sought comment on this proposal.

We received one public comment on the proposed updates to web-broker operational readiness review requirements. The following is a summary of the comment we received and our response.

Comment: One commenter indicated they did not object to this proposal because it primarily codifies existing guidelines to which web-brokers are already subject. While acknowledging that similar requirements may not apply to QHP issuers, based in part on their status as HIPAA-covered entities, the commenter recommended similar requirements apply to non-web-broker QHP issuer direct enrollment technology providers. The commenter went on to state that though these entities may also be subject to HIPAA as issuers' business associates, issuers may not apply the same type of security and privacy oversight that HHS applies to web-brokers.

Response: We are finalizing this proposal as proposed. We appreciate the recommendation to extend similar or identical requirements to non-web-broker QHP issuer direct enrollment technology providers, and may consider proposing such requirements in the future. However, we did not propose and are not finalizing the extension of the same additional operational readiness review requirements to QHP issuers participating in the FFE direct enrollment program. As noted above and explained in the proposed rule, we did not propose to extend the same requirements to QHP issuers because, as HIPAA-covered entities, issuers are

subject to longstanding federal privacy and security requirements that are not necessarily applicable to all web-brokers. In recognition of the applicability of the HIPAA privacy and security framework and extensive oversight of issuers by state regulators, HHS adopted a different approach for QHP issuer operational readiness reviews, which includes not imposing certain requirements applicable to web-broker direct enrollment entities. While we continuously review our approach and regularly evaluate whether to enhance program requirements for all direct enrollment entities, we believe the current approach strikes the appropriate balance between the burden associated with program requirements for different types of direct enrollment entities and the risks posed by those entities' participation in the program. In addition, our experience to date has shown that most direct enrollment technology providers that develop technology platforms for purposes of facilitating QHP issuer use of direct enrollment are either facilitating participation in the EDE program or are also web-brokers, and therefore would be subject to the more rigorous EDE operational readiness review requirements or the operational readiness review requirements applicable to web-brokers. To the extent a small number of QHP issuer direct enrollment technology providers are not also web-brokers and are not subject to the more rigorous EDE operational readiness review requirements, those entities are likely subject to HIPAA as issuers' business associates as the commenter acknowledged. As part of our continuous review and evaluation of direct enrollment requirements, we intend to monitor the types of entities QHP issuers engage with as direct enrollment technology providers and may propose changes to the operational readiness review requirements for QHP issuer direct enrollment technology providers in future rulemaking.

5. Standards for Direct Enrollment Entities and for Third Parties to Perform Audits of Direct Enrollment Entities (§ 155.221)

a. Direct Enrollment Entity Plan Display Requirements

We proposed to revise § 155.221(b)(1) to clarify the requirements that apply when direct enrollment entities want to display and market QHPs¹⁸⁸ and non-QHPs. We proposed that in such circumstances, the web-broker or QHP issuer must display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain proposed exceptions described below.

In the 2020 Payment Notice final rule, we amended § 155.221(b)(1) to require direct enrollment entities to display and market QHPs and non-QHPs on separate website pages on their respective non-Exchange websites.¹⁸⁹ Similarly, we amended paragraph (b)(3) to require direct enrollment entities to limit the marketing of non-QHPs during the Exchange eligibility application and QHP 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.¹⁹⁰ Under the existing display standards captured at paragraphs (b)(1) and (3), direct enrollment entities are required to offer an Exchange eligibility application and QHP selection process that is free from advertisements or information about non-QHPs and sponsored links promoting health insurance related products. However, under the current framework, it is 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 complies with the applicable requirements. We explained in the 2020 Payment Notice that we believe marketing some products in conjunction with QHPs may

¹⁸⁸ As detailed in prior rulemaking, with some limited exceptions, stand-alone dental plans certified for sale on an Exchange are considered a type of QHP. See 77 FR 18315. CMS expects direct enrollment entities to follow the same requirements for stand-alone dental plan QHPs as for medical QHPs, including the applicable display and marketing requirements captured in §§ 155.220, 155.221, and 156.1230, except as proposed and finalized at new § 155.221(c)(2) in the context of off-Exchange stand-alone dental plan shopping.

¹⁸⁹ See 84 FR 17523 and 17524.

¹⁹⁰ *Id.*

cause consumer confusion, especially as it relates to the availability of financial assistance for QHPs purchased through the Exchanges.¹⁹¹ We acknowledged at that time that we may need to update these standards 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 are in place.¹⁹²

In the proposed rule, we proposed to amend paragraph (b)(1) to refine the previously adopted policy, consistent with the original intent of minimizing consumer confusion about distinct products with substantially different characteristics, while providing direct enrollment entities with more marketing flexibility and opportunities for innovation. QHPs are required to be offered on- and off-Exchange under the guaranteed availability requirements at § 147.104. The current framework allows for direct enrollment entities to display on- and off-Exchange QHPs on the same website pages, as long as the direct enrollment entity's website makes clear that APTC and CSRs are only available for QHPs offered through the Exchange.¹⁹³ We noted that we have observed various attempts by direct enrollment entities to distinguish between on- and off-Exchange QHPs displayed on the same website pages, but believed that even good faith efforts to inform consumers about this distinction have the potential to cause confusion about which QHP a consumer should select if APTC-eligible when two instances of otherwise identical plans (that is, the on- and off-Exchange versions of the QHP) are displayed on a single website page, but only one is available with APTC. In addition, paragraph (b)(1) currently prohibits the display of off-Exchange QHPs on the same website pages as comparable non-QHP individual health insurance coverage. This creates a segmented off-Exchange plan shopping experience on direct enrollment entity websites that does not allow consumers to easily comparison shop

¹⁹¹ Id.

¹⁹² Id.

¹⁹³ See, for example, 45 CFR 155.220(j)(2)(i) and 156.1230(a)(1)(iii).

among comparable major medical health insurance products. As described in the proposed rule and further below, the recent introduction of individual coverage health reimbursement arrangements (HRAs) increases the importance of individual health insurance coverage offered outside of the Exchange for employees whose employers offer such arrangements and also offer the opportunity to make salary reduction contributions through a cafeteria plan under section 125 of the Code, and this is part of the reason we proposed to amend the current display requirements for direct enrollment entities.

We proposed to revise § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. Requiring that these three categories of products be displayed and marketed on separate website pages provides a more precise delineation between the three categories of products with substantially different characteristics, either in the way they can be purchased or the types of benefits they offer, while still allowing substantial flexibility in website design to facilitate the consumer's shopping experience. We proposed the first product category, QHPs offered through the Exchange, must be isolated from the other categories of products to distinguish for consumers the products for which APTC and CSRs are available (if eligible). We proposed the second product category, individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), must be similarly distinguished from other products, because those plans represent major medical coverage that is subject to the same ACA market-wide requirements as QHPs offered through the Exchange, but that is not available with APTC and CSRs. Therefore, distinguishing between these two categories of products by requiring that they be displayed and marketed on separate website pages would allow consumers to more easily shop for comparable major medical insurance subject to ACA market-wide rules while maintaining the clear distinction between plans for

which APTC and CSRs are and are not available. We proposed that the third product category, which encompasses types of products not in the first two categories, including excepted benefits, must be displayed and marketed on one or more website pages separate from the website pages used for displaying and marketing the first two categories of products to assist consumers in distinguishing them from major medical plans. The range of products in the third category are not subject to ACA market-wide rules and APTC and CSRs are not available for such products, and therefore they are substantially different from the plans that fall into the first two categories.

We also proposed to amend § 155.221(b)(3) to include clarifying edits and to include the same exceptions detailed in this final rule as we proposed for paragraph (b)(1). We proposed to revise paragraph (b)(3) to limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers would be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under new proposed paragraph (c)(1). The proposal also removed a redundant reference to “plan” that was included after “QHP,” and added references to “plans” after the references to “products” to use consistent language throughout paragraphs (b)(1) and (3). We proposed the same exceptions for paragraph (b)(3) to align with the proposed changes to paragraph (b)(1) to clarify that displaying QHPs and non-QHPs on the same website page, as would be permitted under the proposed exceptions in certain circumstances, would not constitute a violation of paragraphs (b)(1) or (3).

We proposed certain exceptions in new § 155.221(c) to the proposed updates to paragraphs (b)(1) and (3), because we recognized that, in some limited scenarios, consumers may be best served by being able to directly and easily compare plans offered on- and off-Exchange. As of January 1, 2020, employers may offer employees an individual coverage HRA instead of offering traditional group health coverage.¹⁹⁴ An individual coverage HRA may reimburse

¹⁹⁴ See Health Reimbursement Arrangements and Other Account-Based Group Health Plans; Final rule, 84 FR 28888 (June 20, 2019).

employees for medical expenses, including monthly health insurance premiums. To use the individual coverage HRA, an employee (and any eligible household members) must enroll in individual health insurance coverage, other than excepted benefits, or Medicare parts A and B or C. To satisfy this requirement, employees (and any eligible household members) can enroll in individual health insurance coverage through the Exchange or outside the Exchange. An employee and any household members offered an individual coverage HRA will be ineligible for APTC if the individual coverage HRA is affordable or if the employee and household members accept the individual coverage HRA even if it is unaffordable. If an employee and any household members offered an individual coverage HRA that is unaffordable decline the individual coverage HRA benefit, they may qualify for APTC (if otherwise eligible) if they enroll in a QHP through the Exchange. Some employees who are offered an individual coverage HRA may also be eligible, through a cafeteria plan under section 125 of the Code, to pay a portion of their health insurance premiums through tax-preferred salary reduction contributions. This type of cafeteria plan benefit may only be used in combination with off-Exchange individual health insurance coverage. Employers have flexibility to offer an employee both the individual coverage HRA and the cafeteria plan benefit instead of providing traditional tax-preferred group health coverage. However, employers may not offer employees a choice of an individual coverage HRA or traditional group health coverage.

Consumers shopping and enrolling in coverage through direct enrollment entity websites may therefore wish to see and consider additional non-QHP individual health insurance coverage (other than excepted benefits) options that are only available off-Exchange. We also noted that we believed consumers may find it difficult to determine their best option, especially when they are part of a tax household with members that may have varying eligibility for APTC, CSRs, Medicaid, CHIP, individual coverage HRAs, and cafeteria plans. For this reason, we proposed to provide an exception to the new proposed display standards in § 155.221(b)(1) and (b)(3) to support the development of innovative and consumer-friendly plan comparison tools by direct

enrollment entities to assist consumers in making the best choices among individual health insurance coverage options subject to ACA market-wide rules for themselves and their families in these complex situations.

In proposed new paragraph (c)(1), we proposed to allow direct enrollment entities to display and market QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated, within the website user interface or by communicating to an agent or broker assisting them, they have received an offer of an individual coverage HRA, as a standalone benefit or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage HRA using a salary reduction arrangement under a cafeteria plan, so long as certain conditions are met. As reflected in the new proposed § 155.221(c)(1), the conditions we proposed to adopt included clearly distinguishing between the QHPs offered through the Exchange and the individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicating that APTC and CSRs are available only for QHPs purchased through the Exchange, that APTC is not available to an individual who accepts an offer of an individual coverage HRA or who opts out of an affordable individual coverage HRA, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange.

We noted that we wished to reduce incentives that may lead to routing consumer households to off-Exchange plan shopping experiences based on overly simplistic factors such as a single member of a multi-member household having an individual coverage HRA and a cafeteria plan offer. Instead we sought to encourage direct enrollment entities to develop blended plan selection user interfaces that incorporate on- and off-Exchange plan options when assisting consumers who have communicated receipt of an offer of an individual coverage HRA while

incorporating the proposed conditions that are designed to minimize the chance for consumer confusion about the differences between the different coverage options. For example, a direct enrollment entity exercising the flexibility under the proposed exception in § 155.221(c)(1) could clearly distinguish between on- and off-Exchange plan options by using frames, columns, different color schemes, prominent headings, icons, help text, and other visual aids to increase the chance that consumers are aware of the distinctions between the plan options. We emphasized the proposal's intent was to distinguish and clarify user interface elements to be clear, prominent, and difficult to ignore, and therefore the use of an obscure disclaimer in small text at the bottom of the page or behind a link would not be sufficient, for example. We noted that in addition to the safeguards proposed in the proposed rule, direct enrollment entities in the FFEs are subject to standards of conduct that require they provide consumers with correct information, without omission of material fact, regarding QHPs and insurance affordability programs, and refrain from marketing or conduct that is misleading.¹⁹⁵ We solicited comment on these proposals, as well as comments on alternative approaches through which direct enrollment entities may assist consumers with individual coverage enrollment when they have an offer of an individual coverage HRA.

We proposed an additional exception to § 155.221(b)(1) at proposed paragraph (c)(2) to allow direct enrollment entities to display and market stand-alone dental plans certified by an Exchange but offered outside the Exchange and non-certified stand-alone dental plans on the same off-Exchange dental plan shopping website pages. Stand-alone dental plans certified by an Exchange and non-certified stand-alone dental plans should be largely comparable products among which consumers looking for dental coverage off-Exchange may wish to comparison shop. Since the proposed change at paragraph (b)(1) to allow display of all individual health

¹⁹⁵ See 45 CFR 155.220(j)(2)(i), applicable to web-brokers, and 156.1230(b)(2), applicable to QHP issuers participating in direct enrollment. Also see "Guidance Regarding Website Display for Direct Enrollment (DE) Entities Assisting Consumers in States with Federally-facilitated Exchanges (FFE) and State Exchanges on the Federal platform (SBE-FPs)." Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/DE-Entity-Standards-of-Conduct-Website-Display.pdf>.

insurance coverage offered outside the Exchange on the same website pages (including QHPs and non-QHPs other than excepted benefits) excludes stand-alone dental plans (since stand-alone dental plans are excepted benefits), we proposed this additional exception to allow direct enrollment entities to provide a consumer-friendly off-Exchange stand-alone dental plan shopping experience where consumers can compare the full range of stand-alone dental plans on a single website page.

We proposed conforming amendments to redesignate paragraphs (c) through (h) in § 155.221 as paragraphs (d) through (i) and related updates to internal cross references. As detailed in the proposed rule and this final rule, we also proposed certain amendments to the direct enrollment entity operational readiness review requirements in § 155.221(b)(4).

We requested comment on these proposals.

We received numerous public comments on the proposed amendments to the direct enrollment entity plan display requirements. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposal to require direct enrollment entities to display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages. One commenter stated that guardrails should limit opportunities for consumers to accidentally enroll in or be steered toward a non-subsidized QHP or non-QHP; and therefore, at a minimum, substantially different coverage types should be listed on separate website pages (as proposed) to ensure consumers compare apples-to-apples. Other commenters expressed similar sentiments, and in some cases advocated for the inclusion of additional safeguards to help consumers understand the different products that might be displayed to them (for example, requiring that different products be clearly labeled to aid in differentiation). A few commenters requested clarification about which of the categories would include products or services such as

health care sharing ministries, direct primary care arrangements, group association plans, and short-term limited duration insurance, or requested confirmation that such products or services would have to be displayed on the one or more website pages that included excepted benefits and not on the website pages that display on- or off-Exchange QHPs and non-QHPs other than excepted benefits. Several commenters expressed opposition to the proposal. Generally these commenters cited concerns about consumer confusion if and when consumers are presented with numerous substantially different product options, regardless of how those products are displayed and even if they are displayed on separate website pages.

Response: We are finalizing the proposal as proposed, but hope to clarify several issues raised by commenters. We intend to carefully monitor how direct enrollment entities modify their websites in accordance with these requirements and anticipate making updates in future rulemaking if we believe such updates are necessary to mitigate the risk that consumers are confused by how different products are being displayed or marketed to them on direct enrollment entity websites. We agree that guardrails are necessary to help consumers understand their options and minimize the chance they inadvertently choose to enroll in a plan or product that they did not intend to enroll in or that does not meet their needs. As we monitor direct enrollment websites, we will evaluate whether the user interface options direct enrollment entities choose (for example, how they convey to consumers the characteristics of different products or services on different website pages) are adequate in terms of helping consumers distinguish between and understand the advantages and disadvantages of different products or services. When designing their websites, we encourage direct enrollment entities to incorporate clear labels or descriptions of different products or services they offer to assist consumers, and we may require specific labeling or description requirements in future rulemaking if we determine such standardization would be helpful for consumers or if we identify other opportunities to improve the consumer experience and better inform consumers about the important differences between substantially different products or services marketed or displayed on direct enrollment entity websites. We

also clarify and confirm that, as applied to the other non-QHP products and services identified by commenters, § 155.221(b)(1) requires that any marketing or display of health care sharing ministries, direct primary care arrangements, group association plans, and short-term limited duration insurance not occur on the same website pages as on- or off-Exchange QHPs and non-QHPs other than excepted benefits. When marketed or displayed on direct enrollment entity websites, those products and services should instead be displayed on the separate website page or pages reserved for all other products, such as excepted benefits. The intent of these amendments is to provide additional clarity to direct enrollment entities regarding the display and marketing of products or services that are not subject to ACA market-wide rules and on- and off-Exchange QHPs, as well as non-QHP major medical coverage that is subject to ACA market-wide rules. We appreciate the concerns expressed by some commenters that consumers may still be confused when presented with numerous substantially different options for products or services, even if those products or services are displayed on separate website pages in a clear manner. As described in the proposed rule and the preamble above, a significant motivation for adopting this policy was to reduce consumer confusion about distinct products with substantially different characteristics. We acknowledge that this approach may not eliminate all consumer confusion or other risks that may exist for consumers when they use direct enrollment and other non-Exchange websites. We intend to carefully monitor direct enrollment websites and may pursue refinements to these website display requirements in future rulemaking. We are also broadly considering options for future rulemaking intended to address risks to consumers that use direct enrollment websites not addressed by this policy, including evaluating consumer protections adopted by State Exchanges.

Comment: There were several comments received related specifically to the portion of the proposed rule that would allow direct enrollment entities to display and market QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when

assisting individuals who have communicated they have received an offer of an individual coverage HRA. Several commenters supported the flexibility provided by this exception. One commenter recognized the need to provide consumers with individual coverage HRA offers information about all relevant coverage options, but expressed concern about consumers being misled or confused about those options and urged HHS to strictly enforce requirements related to the proposed exception. Another commenter acknowledged that consumers offered individual coverage HRAs will need access to information for both on- and off-Exchange options, but opposed the proposed exception, stating that allowing on- and off-Exchange options to be commingled on the same website page would lead to substantial confusion, even with smart design choices to differentiate the plans. One commenter recommended that the exception be modified so that it is available generally (without respect to whether a specific consumer the entity is assisting has been offered an individual coverage HRA) to entities approved to use EDE that have implemented eligibility application functionality supporting individual coverage HRA offers. The commenter stated this alternative approach would be less burdensome to implement than accounting for specific consumers' situations. One commenter noted this exception as proposed does not apply to consumers provided QSEHRAs, and that if it is modified to account for such plans, a requirement should be included that direct enrollment entities communicate to consumers the need to reduce APTC by any employer contribution.

Response: We appreciate the comments and are finalizing this exception as proposed. We note that the individual coverage HRA market is relatively new and still evolving, and recognize that the flexibility and requirements associated with this exception should be monitored closely and evaluated regularly for potential modifications in future rulemaking. We further recognize there is the potential for confusion, even with strict compliance with the safeguards we are finalizing. We believe this exception and the other related direct enrollment entity plan display requirement proposals finalized in this rule represent a reasonable balance at this time and appropriately take into account the need to also support consumers who may be offered new

types of coverage arrangements (for example, individual coverage HRAs). Additionally, we intend to closely monitor implementation of the exception and the accompanying display requirement proposals finalized in this rule through website reviews and will strictly enforce the limitations and requirements related to leveraging this exception, and will make adjustments through future rulemaking if deemed necessary. We further note that most consumers using direct enrollment websites are assisted by agents or brokers who can help their clients understand their options. To help consumers offered individual coverage HRAs navigate their different options and to support agents and brokers providing assistance to these consumers, HHS has developed various education, training, and other materials on individual coverage HRAs.¹⁹⁶ As stated in the proposed rule, we hope that this exception will lead direct enrollment entities to design and implement innovative and consumer-friendly plan comparison tools to assist consumers offered individual coverage HRAs in making the best choices for themselves and their families in these complex situations. In addition, we sought to reduce incentives that may lead direct enrollment entities to route consumer households to off-Exchange plan shopping experiences based on overly simplistic factors such as a single member of a multi-member household having an individual coverage HRA and a cafeteria plan offer.¹⁹⁷ As a result of the comments received expressing concerns about consumer confusion due to this exception, we encourage any direct enrollment entity considering updates to its website design to leverage this exception to contact us before implementing any updates (by emailing directenrollment@cms.hhs.gov). We are interested in working collaboratively with direct enrollment entities to ensure their planned website designs meet applicable regulatory requirements and intend to carefully monitor implementation under this exception. We would pursue any refinements through rulemaking, and if we deem necessary or appropriate may also

¹⁹⁶ See, for example, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Health-Reimbursement-Arrangements>.

¹⁹⁷ There are additional complexities for APTC-eligible consumers who receive an offer of an individual coverage HRA that is unaffordable in addition to a salary reduction arrangement under a cafeteria plan. See, for example, 85 FR at 78617.

consider adopting a mandatory review and approval process before direct enrollment entities could leverage this exception in a future rulemaking.

We do not agree with the one commenter that suggested this exception be made broadly available to EDE entities, without respect to whether a specific consumer the entity is assisting has been offered an individual coverage HRA. This exception is intended to be a targeted measure focused on supporting consumers offered individual coverage HRAs who use direct enrollment entity websites to shop for coverage.¹⁹⁸ In those instances, it would be appropriate to inform consumers about the broader range of individual health insurance coverage options. The same considerations do not exist for consumers who do not receive individual coverage HRA offers. Direct enrollment entities already design different plan shopping interfaces for their websites and route consumers to them based on screening questions intended to evaluate specific consumers' needs and circumstances. For entities assisting consumers with individual coverage HRA offers, leveraging the flexibility afforded by the exception finalized in this rule could be accomplished using a similar approach of asking consumers questions about whether they have received an individual coverage HRA offer and routing them to different website pages based on their responses. Finally, we note that we did not propose and are not finalizing an extension of the proposed exception to consumers provided QSEHRAs at this time, in part because we have not noted the same interest in serving such consumers from direct enrollment entities. We may consider creating such an exception in a future rulemaking if necessary or appropriate.

Comment: We received a small number of comments related to the proposed exception to § 155.221(b)(1) at proposed paragraph (c)(2) to allow direct enrollment entities to display and market stand-alone dental plans certified by an Exchange but offered outside the Exchange and non-certified stand-alone dental plans on the same off-Exchange dental plan shopping website

¹⁹⁸ As detailed in the proposed rule, the recent introduction of individual coverage HRAs increases the importance of individual health insurance coverage offered outside of the Exchange for employees offered such arrangements alongside the opportunity to make salary reduction contributions through a cafeteria plan under section 125 of the Code. See 85 FR 78616.

pages. One commenter stated that dental plans offer a wide variety of plan designs, and suggested that if the proposed stand-alone dental plan exception is finalized, it should include a requirement that direct enrollment entities clearly label different types of dental plans. The commenter also expressed concern that consumers may not be able to differentiate between stand-alone dental plans for which APTC may be used and stand-alone dental plans only available off-Exchange. Another commenter requested implementation of the proposed stand-alone dental plan exception be delayed until testing the approach with consumer focus groups and evaluating its impact based on that testing.

Response: We appreciate the comments and are finalizing this proposal as proposed. As mentioned above, when designing their websites, we encourage direct enrollment entities to incorporate clear labels or descriptions of different plans, products, or services they offer to assist consumers, whether major medical or stand-alone dental plans. We may require specific labeling or description requirements in future rulemaking if we determine such standardization would be helpful for consumers or if we identify other opportunities to improve the consumer experience and better inform consumers about the important differences between substantially different plans, products, or services. We also clarify that since the stand-alone dental plan exception is only available to direct enrollment entities with regard to their off-Exchange stand-alone dental plan shopping websites, the risk that a consumer may inadvertently choose a stand-alone dental plan for which APTC is not available is not relevant since APTC is not available for any off-Exchange stand-alone dental plans. Stated differently, an APTC-eligible consumer seeking to enroll in a stand-alone dental plan on-Exchange that has wound up shopping for stand-alone dental plans on an off-Exchange website has encountered a problem unrelated to the stand-alone dental plan exception in this rule. While we understand the request to delay implementation of the stand-alone dental plan exception until consumer focus group testing can be conducted, we consider multiple factors when developing rules, including risk of consumer harm, impact to the operations of the private business entities we are regulating, and the availability of government

resources to conduct testing and oversight, among other factors. We also believe this exception is sufficiently narrow for the proposal to be finalized as part of this rule because it is limited to website pages marketing and facilitating enrollment in off-Exchange plans, products, and services. In addition, until the current rule at § 155.221(b)(1) was finalized in 2019, this exception would not have been required for entities to display stand-alone dental plans in this manner and we suspect many entities were doing so at the time. As mentioned above, we will be closely monitoring and evaluating how direct enrollment entities modify their websites based on these updated rules and will pursue future rulemaking if we believe that is necessary or appropriate. We may also engage in consumer focus group testing in the future, if deemed necessary or appropriate.

b. Direct Enrollment Entity Operational Readiness Review Requirements

We proposed to revise § 155.221(b)(4) to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new proposed § 155.220(c)(6), we proposed these amendments to codify in § 155.221(b)(4) more details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We noted that these proposed requirements are in addition to the operational readiness requirements for web-brokers at new proposed § 155.220(c)(6), although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in the direct enrollment program and the source and type of documentation. For example, a web-broker seeking to participate only in the Classic DE program would only be required to meet the operational readiness requirements at new proposed § 155.220(c)(6), whereas a web-broker seeking to participate in the EDE program may be permitted to use its third-party security and privacy audit

documentation for EDE to satisfy the security and privacy audit documentation requirements of §§ 155.220(c)(6) and 155.221(b)(4) assuming the Classic DE and EDE systems and functionality were hosted in the same environments subject to the third-party audit.

In paragraph (b)(4), we proposed to continue to require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We added new proposed paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit or complete, in the form and manner specified by HHS, a number of artifacts, documentation, or various testing or training processes. The documentation may include business audit documentation, including: notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results. Submission of agreements between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program may also be required. Required testing may include eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in the direct enrollment program.

We requested comment on this proposal.

We received one public comment on the proposed updates to direct enrollment entity operational readiness review requirements. The following is a summary of the comment we received and our response.

Comment: One commenter expressed support for the proposed updates to the direct enrollment entity operational readiness review requirements.

Response: We appreciate the commenter's support of the proposed updates to the direct enrollment entity operational readiness review requirements and are finalizing this proposal as proposed.

6. Certified Applications Counselors (§ 155.225)

In the proposed rule, we proposed to allow, but not require, CACs to assist consumers with applying for insurance affordability programs and QHP enrollment through web-broker non-Exchange websites under certain circumstances and to the extent permitted by state law. For a discussion of this proposal, along with a summary of comments received and our responses to these comments, please see the preamble for § 155.220.

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

a. Verification of Eligibility for Employer Sponsored Coverage

Exchanges must verify whether an applicant is eligible for or enrolled in an eligible employer sponsored plan for the benefit year for which coverage and premium assistance (APTC or CSR) are requested using available data sources, if applicable, as described in § 155.320(d)(2). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in paragraph (d)(2)(i) through (iii), an alternate procedure applies. Specifically, Exchanges must select a statistically significant random sample of applicants and meet the requirements under paragraph (d)(4)(i). For benefit years 2016 through 2019, Exchanges also could use an alternative process approved by HHS. We are continuing to explore a new alternative approach to replace the current procedures in paragraph (d)(4)(i), under which an Exchange may design its verification process to confirm that qualified individuals are not eligible for or enrolled in an eligible employer sponsored plan, disqualifying them from receiving APTC or CSRs.

HHS's experience conducting random sampling revealed that employer response rates to HHS's request for information were low. The manual verification process described in § 155.320(d)(4)(i) requires significant resources and government funds, and the value of the results ultimately does not appear to outweigh the costs of conducting the work because only a small percentage of sample enrollees have been determined by HHS to have received APTC or CSRs inappropriately. We believe an approach to verifying an applicant's attestation regarding access to eligible employer sponsored coverage should be rigorous, while posing the least amount of burden on states, employers, consumers, and taxpayers. Based on our experiences with random sampling methodology under paragraph (d)(4)(i), HHS is of the view that this methodology may not be the best approach for all Exchanges to assess the associated risk for inappropriate payment of APTC and CSRs. As such, in 2019, HHS conducted a study to (1) determine the unique characteristics of the population with offers of employer-sponsored coverage that meets minimum value and affordability standards, (2) compare premium and out-of-pocket costs for consumers enrolled in affordable employer-sponsored coverage to Exchange coverage, and (3) identify the incentives, if any, that drive consumers to enroll in Exchange coverage rather than coverage offered through their current employer. We are still evaluating the results of this study to ensure the best verification process to ensure that consumers with offers of affordable coverage that meets affordability and minimum value standards through their employer are identified and do not receive APTC or CSRs inappropriately. HHS will consider changes to the verification process outlined under paragraph (d)(4) as part of future rulemaking.

As HHS continues to explore the best options for verification of employer sponsored coverage, we proposed that HHS will continue to refrain from taking enforcement action against Exchanges that do not perform random sampling as required by paragraph (d)(4), as an alternative to performing this verification against the data sources required under §155.320(d)(2)(i) through (iii), and will extend this non-enforcement posture from plan year 2021 through plan year 2022. We also proposed that HHS will continue to exercise such

discretion as HHS continues to evaluate the results of the employer verification study described in the proposed rule and of the futures changes also discussed.

Comment: The majority of commenters on this topic agreed with HHS's proposal to refrain from taking enforcement action against Exchanges that do not conduct random sampling to verify whether an applicant has access to or received an offer of affordable coverage that meets the minimum value standard through their employer. The commenters agreed with HHS's prior study findings that the random sampling process requires significant resources with little return on investment. Commenters also agreed with HHS that an employer-sponsored coverage verification approach should provide State Exchanges with flexibility and more opportunities to use verification processes that are evidence-based, while imposing the least amount of burden on consumers, states, employers, and taxpayers and ensures that only consumers who are eligible for APTC/CSRs continue to receive them; commenters noted that this is especially important during the current COVID-19 public health emergency and allows states to shift resources to help consumers retain or enroll in QHP coverage. One commenter further noted that an efficient verification process to verify whether an applicant has an offer of affordable coverage through their employer also provided an added benefit as it reduces the employer shared responsibility payment (ESRP) burden for both the Internal Revenue Service (IRS) and employers nationwide. One commenter supported the proposal, but proposed that HHS allow State Exchanges to select their own verification method that would not add significant administrative burden on states and stated that the current proposal does not provide State Exchanges with enough flexibility to make any necessary changes that may result from future rulemaking.

Finally, another commenter suggested that, as HHS reviews the results of the study discussed in the preamble to the proposed rule, we should consider releasing the results of the 2019 study in an effort to provide transparency regarding the demographic patterns that HHS discovered as a result of this research.

Response: We agree that the current random sampling process required under § 155.320(d)(4)(i) is not only burdensome for states, employers, consumers, and taxpayers, but it also does not provide enough flexibility to all Exchanges to develop a process for employer-sponsored coverage verification that more accurately reflects their respective enrolled Exchange populations. As discussed in the preamble above and in the proposed rule, HHS shares the same concerns regarding the feasibility and effectiveness of random sampling, including the effectiveness of employer and employee notices, and the impact that such a verification process has on Exchanges' appeals processes. We also agree that a verification process should be evidence-based and informed by certain risk-factors for inappropriate payment of APTC/CSRs and that additional flexibilities are important to help states better serve their populations during the current COVID-19 public health emergency. Finally, as HHS continues to evaluate the results of the 2019 study, we will explore the possibility of releasing the results of the study at a later date.

We disagree with the comment that the proposal to extend enforcement discretion to plan year 2022 provides State Exchanges with less flexibility to implement any future process changes for employer-sponsored coverage verification. State Exchanges have existing flexibility under §§ 155.320(a)(2) and 155.315(h) to propose an alternative approach to using the verification procedures under § 155.320(d)(2), or an alternative to using the random sampling process described under § 155.320(d)(4), in order to verify whether applicants have received an offer of affordable coverage. We continue to encourage states to use this flexibility to explore evidence or risk-based approaches to conducting this verification. Finally, these changes do not impact State Exchanges that currently verify offers of employer-sponsored coverage using approved data sources under § 155.320(d)(2)(i) through (iii) or use the random sampling procedures under § 155.320(d)(4), and have determined these methods are the appropriate approaches for their Exchanges to meet requirements under § 155.320(d).

Comment: Two commenters supported the proposal but expressed their ongoing concerns regarding employer-sponsored verification, specifically that the lack of a centralized website or database for employers to provide contact information and other information Exchanges would need to verify whether an employer offers coverage that meets minimum value standards is problematic and has led to many of the ongoing challenges Exchanges have experienced. These commenters suggested that HHS and IRS should work together to develop a single, streamlined verification process that could be achieved in one of two ways: 1) by establishing a simple, web-based platform or database where employers could provide Exchanges with their contact information which Exchanges could query as part of their verification attempts or 2) provide employers with the option to report their information to IRS well in advance of Open Enrollment so that Exchanges could query this information to verify whether that employer offers coverage that meets the employer shared responsibility affordability and minimum value tests. Commenters also urged IRS and Treasury to allow employers to provide real-time employer coverage data on HealthCare.gov to help consumers compare coverage offered through their employers with options offered on Exchanges to make the best coverage decisions based on their needs and budgets.

Response: We did not propose policies or requirements related to future verification processes as HHS is still evaluating the results of the 2019 study to determine the best path forward. HHS appreciates the suggested approaches for consideration and agrees with the commenters that having accurate, up-to-date contact information for employers presents a significant challenge for Exchanges attempting to verify an applicant's attestation that they do not have access to affordable coverage through their employer as outlined under § 155.320(d)(4)(i)(D). HHS will continue to explore all options to implement a verification process for employer-sponsored coverage that is evidence-based and will continue to work with our federal partners to assess the feasibility of creating such a web-based platform or database to collect employer contact information as outlined above.

b. Verification Process Related to Eligibility for Insurance Affordability Programs

As noted in section IV of the preamble, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et al. v. Cochran*, No. 18-2364, 2021 WL 825973 (D. Md. Mar. 4, 2021), vacating certain requirements under 45 CFR 155.320, which provides Exchange income verification requirements for resolving data matching issues related to eligibility for advance payments of premium tax credits. Under the current regulation, an individual who attests to a household income within 100 percent to 400 percent of the federal poverty level (FPL), but whose income according to trusted electronic data sources is below 100 percent FPL, must submit additional documentation supporting the attested to household income.¹⁹⁹ Given the court's order invalidating this policy, we are finalizing revisions to § 155.320 in this final rule to rescind text implementing the policy.

As explained below in the Implementation of the Decision in *City of Columbus, et al. v. Cochran* section, HHS's systems automatically generate requests for income verification information for those with income data matching issues, and it will take some time to redesign this function. Until that redesign is complete and implemented, however, HHS will be able to identify consumers who receive requests for income verification information as a result of current system logic. We have established a manual process to notify those consumers that they need not provide the requested information.

8. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for APTC

We proposed to add new flexibility to allow current Exchange enrollees and their dependents to enroll in a new QHP of a lower metal level²⁰⁰ if they qualify for a special

¹⁹⁹ See 83 FR 16985-16987 (discussing finalization of new paragraphs § 155.320(c)(3)(iii)(D) and (E), and modifications to paragraphs (c)(3)(vi)(C), (D), (F), and (G)).

²⁰⁰ Section 1302(d) of the ACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the ACA. Consumer-facing

enrollment period due to becoming newly ineligible for APTC. We are finalizing a modified version of this policy to permit Exchange enrollees who qualify for a special enrollment period based on a loss of APTC eligibility to change to a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024.

In 2017, the Market Stabilization Rule addressed concerns that Exchange enrollees were utilizing special enrollment periods to change plan metal levels based on ongoing health needs during the coverage year, negatively affecting the individual market risk pool. The Market Stabilization Rule set forth requirements at § 155.420(a)(4) to limit Exchange enrollees' ability to change to a QHP of a different metal level when they qualify for, or when a dependent(s) newly enrolls in Exchange coverage through, most types of special enrollment periods.²⁰¹

Generally, § 155.420(a)(4) provides that enrollees who newly add a household member through most types of special enrollment periods may add the household member to their current QHP or enroll them in a separate QHP,²⁰² and that if an enrollee qualifies for certain special enrollment periods, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b). However, even prior to the change that we are finalizing in this rule, § 155.420(a)(4) included certain flexibilities to permit enrollees to change metal levels through a special enrollment period related to a change in financial assistance for coverage through the Exchange. For example, § 155.420(a)(4)(ii)(B) provides that beginning January 2022, if an enrollee and his or her dependents become newly ineligible for cost-sharing

HealthCare.gov content explains that metal levels serve as an indicator of “how you and your plan split the costs of your health care,” noting that lower levels such as bronze plans have lower monthly premiums but higher out of pocket costs, while higher levels such as gold plans have higher monthly premiums but lower out of pocket costs. See <https://www.healthcare.gov/choose-a-plan/plans-categories/>.

²⁰¹ These limitations do not apply to enrollees who qualify for certain types of special enrollment periods, including those under § 155.420(d)(4), (8), (9), (10), (12), and (14). While special enrollment periods under paragraphs (d)(2)(i) and (d)(6)(i) and (ii) are excepted from § 155.420(a)(4)(iii), § 155.420(a)(4)(i) and (ii) apply other plan category limitations to them.

²⁰² Section 155.420(a)(4)(i), (a)(4)(iii)(B), and (a)(4)(iii)(C) also provide that alternatively, if the QHP's business rules do not allow the newly-enrolling household member to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b).

reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a QHP one metal level higher or lower, if they elect to change their QHP enrollment, which they may wish to do based on loss of previously-available financial assistance.

Similarly, we proposed to add a new flexibility at § 155.420(a)(4)(ii)(C) to allow enrollees and their dependents who become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of a lower metal level. Under this proposal, these special enrollment periods in paragraph (d)(6)(i) and (ii) for becoming newly ineligible for APTC would be addressed in paragraph (a)(4)(ii)(C), and so they will no longer be subject to the separate rules in paragraph (a)(4)(iii). Therefore, we further proposed to revise paragraph (a)(4)(iii) to include them in the list of triggering events excepted from the limitations at paragraph (a)(4)(iii). We are finalizing a modified version of this policy to permit Exchange enrollees who qualify for a special enrollment period based on a loss of APTC eligibility to change to a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024. We expect that that providing Exchanges with more time to implement the change and exempting this special enrollment period from limitations entirely will reduce Exchanges' implementation burden and that this policy will help impacted enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of a potentially significant change to their out of pocket costs.

We proposed this new flexibility in part because of concerns from agents and brokers that some consumers who qualify for the special enrollment period in accordance with § 155.420(d)(6)(i) or (ii) because they lose eligibility for APTC based on an income increase may lose a significant amount of financial assistance without having gained enough income to continue to afford the coverage they selected when APTC was available to them. In the proposed rule, we provided an example of a qualified individual whose estimated annual household

income increases to more than 400 percent FPL due to an income increase of less than \$2,000.²⁰³

In this example, the individual's loss of APTC would require them to pay over \$7,000 more annually for their current plan.²⁰⁴ While this individual would qualify for a special enrollment period due to a loss of eligibility for APTC per paragraph (d)(6)(i), under the previous rule they would not be able to change from a gold plan to a silver or bronze plan (or to a catastrophic plan, if they were eligible) to pay a lower monthly premium, because paragraph (a)(4)(iii)(A) provided that these enrollees may only change to another QHP within their current plan's metal level.

The American Rescue Plan Act of 2021 will help some individuals in the situation described above because it allows individuals whose household income exceeds 400 percent FPL to qualify for a premium tax credit if they are otherwise eligible. The new law will make premium tax credits available to these families and caps the amount of household income the family is expected to contribute to their premiums for purposes of calculating the credit at 8.5 percent, based on the cost of their second lowest cost silver benchmark plan. However, this flexibility is also necessary to ensure access to coverage by those who experience circumstances other than a household income increase that may cause consumers to become ineligible for APTC. For example, in the proposed rule, we also noted that Exchange enrollees can lose eligibility for APTC due to a change in tax household size, without experiencing any change in income, and we provided an example of a family of two parents and a 20-year old child with no income and who is not a full-time student. We are updating the example to reflect the changes made for 2021 and 2022 by the American Rescue Plan Act of 2021. If the family applies during open enrollment in 2022 and qualifies for APTC based on a household of three, and during 2023 the child becomes employed and earns enough income so that the parents no longer plan to claim the child as a tax dependent for 2023, their decrease in household size could cause them to lose

²⁰³ See 85 FR 78623.

²⁰⁴ 26 CFR 1.36B-2(b)(1) provides that to be eligible for a premium tax credit, the taxpayer's household income must be at least 100 percent but not more than 400 percent of the FPL for the taxpayer's family size for the taxable year. Per the HHS Poverty Guidelines for 2020, 400 percent of the FPL for 2020 for an individual in the contiguous 48 states and DC is \$51,040. However, under the American Rescue Plan Act of 2021, for taxable years 2021 and 2022, the upper limit on household income at 400 percent of the FPL has been removed.

eligibility for APTC. Loss of eligibility for APTC based on not being permitted to claim as a tax dependent an individual projected at open enrollment to be a tax dependent (loss of a projected tax dependent) is likely a less common challenge, because loss of a projected tax dependent who was previously enrolled in the same plan as other household members may also result in a lower premium for remaining household members. However, in some cases the decrease in premium may not be enough to make up for the loss of APTC.

As discussed in the proposed rule, in many cases individuals enrolling in Exchange coverage during open enrollment will not anticipate experiencing a situation in the middle of the plan year like those described in this final rule. Even if they are aware that they could have a small increase in household income or lose a projected tax dependent, they may not realize that these changes could make them newly ineligible for APTC. Furthermore, sometimes these changes are not foreseeable. Additionally, it is reasonable for individuals who complete an application and then shop for coverage on HealthCare.gov to select a QHP based on premiums that are reduced by the APTC amount for which they are eligible at the time of plan selection, particularly if they do not realize that their financial assistance could change based on loss of a projected tax dependent or a small household income change during the coming year.

While this proposal was designed to provide Exchange enrollees who lose APTC with the chance to select lower-cost coverage, we recognized that changing to a new QHP mid-plan year may cause enrollees to incur additional out of pocket costs as a new QHP selection typically resets the deductible and other accumulators. We believe that Exchange enrollees who lose APTC eligibility are best able to weigh the trade-off between reset accumulators or maintaining an affordable monthly premium. As discussed in the proposed rule, a change may benefit some consumers because price differences between QHPs of different metal levels can be significant. For example, in states using the federal enrollment platform, on average, silver plan premiums are 34 percent more expensive than bronze plan premiums, and gold plan premiums are

14 percent more expensive than silver plan premiums.²⁰⁵ Further, enrollees who qualify to make a new plan selection for an applicable special enrollment period already must consider this question.

Finally, in the proposed rule we acknowledged that enrollees may lose APTC eligibility and qualify for a special enrollment period due to their APTC loss for a reason other than a change in household income or tax family size. For example, a currently-enrolled individual or household could lose APTC and qualify for the related special enrollment period due to an expired inconsistency regarding projected annual household income, or because the Exchange has information that they are eligible for or enrolled in other qualifying coverage that is considered MEC such as most Medicaid coverage, CHIP, or the Basic Health Program (BHP), through the periodic data matching process described in § 155.330(d), and therefore are ineligible for APTC. We sought comment on whether stakeholders had concerns with this possibility, and on how HHS can help ensure that enrollees who lose eligibility for APTC because of failure to provide information to the Exchange to confirm their APTC eligibility can understand and take action on steps needed to do so. Relatedly, we sought comment on whether Exchanges should limit the flexibility proposed in this rule only to enrollees who qualify for a special enrollment period because they lost APTC eligibility due to a change in household income or tax family size, and continue to apply the current rule at 155.420(a)(4)(iii)(A) to enrollees who qualify for a special enrollment period because they lost APTC for any other reason. We also sought comment on whether such a policy would impose significant additional burdens on Exchanges.

HHS believed that this proposal is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium.

²⁰⁵ Calculated based on information in the “Plan Year 2020 Qualified Health Plan Choice and Premiums in HealthCare.gov States” report. Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2020QHPPremiumsChoiceReport.pdf>.

However, we requested comment on whether there are concerns with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether we should instead only permit an enrollee to change to a plan one metal level lower than their current QHP. We also requested comment from issuers on whether there are concerns about impacts such as experiencing a decrease in premium receipt from enrollees who opt to change to a lower-cost plan, or whether they view adverse selection as a possibility. We requested comment from Exchanges, in particular, on implementation burden associated with this change to current plan category limitations rules, including on whether we should instead, to reduce this burden, permit current enrollees and currently enrolled dependents who qualify for this SEP to change to a plan of any metal level – that is, simply exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether. We also requested comment from all stakeholders, including those who have or represent individuals with preexisting conditions, on whether such a change would significantly increase risk for adverse selection.

Finally, we also considered whether to propose additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with paragraph (d)(6)(i) or (ii) to change to a QHP of a higher metal level, but we did not propose additional plan flexibility for enrollees who become newly eligible for APTC. We invited comment on whether we should consider additional flexibilities for this population in the future and the anticipated impact of such a policy.

We received public comments on the proposed updates to Exchange enrollees newly ineligible for APTC. The following is a summary of the comments we received and our responses.

Comment: Almost all comments on this proposal were supportive of this change, explaining that allowing enrollees the flexibility to change to a plan of a lower metal level based

on a loss of APTC would allow more individuals to maintain coverage. Some commenters also noted that this proposal could improve the on-Exchange risk pool by increasing the likelihood that individuals would maintain coverage in spite of losing financial assistance. One commenter requested a 2021 effective date for this proposal instead of 2022, and two commenters requested that HHS implement this proposal as soon as possible. One commenter opposed the proposal because they preferred that HHS promote continuous coverage by making more financial assistance available to consumers rather than by providing certain consumers with the flexibility to change to a lower metal level plan. One commenter encouraged HHS to bear in mind the risks of adverse selection in general, but did not oppose this proposal and noted that it would help consumers; this commenter and several others also misunderstood the proposal to be for a new special enrollment period for individuals who lose financial assistance rather than a change to plan category limitations that currently apply to an existing special enrollment period.

No commenters raised the concern that this proposal specifically would increase the risk of adverse selection. Several commenters supported also allowing enrollees who newly become APTC eligible to change to a plan of a higher metal level. Many commenters supported allowing individuals who qualify for a special enrollment period based on a loss of APTC eligibility to change to a plan of any metal level, either to provide enrollees with flexibility to change to the best plan for themselves and their families, to make implementation easier for State Exchanges, or both. One of these commenters requested that instead of applying plan category limitations, HHS require Exchange enrollees to provide documents to confirm their SEP eligibility. Some commenters supported allowing individuals who lose APTC eligibility to change to a plan of a higher or lower metal level rather than just to a plan of a lower metal level. Finally, many commenters disagreed with the need to require plan category limitations in general, and requested that HHS provide Exchanges with flexibility in terms of when or whether to implement plan category limitations at all based on considerations related to their specific State Exchange's market.

Response: We are finalizing a modified version of this policy to permit Exchange enrollees who lose APTC eligibility to change to a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024. We agree with commenters that allowing enrollees to access a plan at any metal level through the existing special enrollment period for those who lose eligibility for APTC will significantly decrease Exchange implementation complexity and cost, and believe that providing Exchanges with the flexibility to implement this change no later than 2024 provides Exchanges with sufficient time to account for this change in their operational planning. We also agree with commenters who stated that providing more flexibility for enrollees who qualify for a special enrollment period due to losing APTC will help consumers who lose eligibility for APTC during the plan year to stay enrolled in coverage by switching to a new QHP that better suits their changed financial situation. While we understand general concerns related to adverse selection, we agree with commenters that this specific policy does not pose this risk because enrollees are likely to access it based on a financial change as opposed to a change in their health care needs. We also clarify that this policy does not create a new special enrollment period qualifying event, but rather is a change to limitations on plan selection that apply to an already-existing special enrollment period for Exchange enrollees who become newly ineligible for APTC per 45 CFR 155.420(d)(6)(i) and (ii).

Additionally, we do not believe that it is necessary to require eligible consumers to submit documentation of the change that resulted in their loss of APTC eligibility, in part because this special enrollment period is triggered automatically when consumers attest to the related income or household change in the application. That is, there is no separate question asking consumers to attest to no longer being APTC eligible. Further, as discussed in the 2017 Market Stabilization Rule, we have concerns about pending a new enrollment until pre-enrollment verification is conducted for current Exchange enrollees; because they would still have an active policy, the potential overlap of current, active policies and pended new

enrollments would cause significant confusion for consumers and create burdens on issuers with respect to managing potential operational issues.²⁰⁶

We did not propose removing plan category limitations; however, we continue to study potential policies to promote continuous coverage and provide consumers with flexibility. Finally, we acknowledge the potential benefit of requiring Exchanges to implement this change quickly, but we believe that providing Exchanges with flexibility to implement it no later than January 1, 2024 strikes an appropriate balance between allowing early implementation if possible and providing Exchanges with necessary flexibility to plan related system updates based on Exchange-specific competing priorities and resources. While some Exchanges may be able to implement this new flexibility sooner than January 1, 2024, in light of competing priorities such as the need to implement changes to calculating financial assistance established in the American Rescue Plan Act of 2021, we believe that substantial flexibility for Exchanges is appropriate.

Comment: Several commenters supported the proposal but responded to our request for comment on the risk that enrollees changing plans mid-coverage year might not realize that their out of pocket costs could increase if their deductible and other accumulators are re-set by noting this is a concern. Some of these commenters requested that HHS provide additional education and outreach to help enrollees to make an informed decision on whether to change to a less expensive plan even though it could require them to meet a new deductible and out-of-pocket maximum without taking into account progress they had made towards these accumulators in their prior coverage. Specific suggestions from commenters included adding pop-up text in the HealthCare.gov application for enrollees changing plans through a special enrollment period, additional notice content, including in the form of infographics, to illustrate the trade-off between a lower cost plan and re-set accumulators, and adding help text to encourage special enrollment period-eligible enrollees to seek out assistance through Find Local Help for assistance with understanding their options. One commenter suggested that related help text should appear

²⁰⁶ 82 FR 18359, <https://www.federalregister.gov/d/2017-07712/p-149>.

at the time of an APTC-ineligibility determination and should also provide these enrollees with the basis for the determination. One commenter asked that HHS reiterate in the final rule that issuers have the flexibility to waive deductibles for consumers who change mid-year to a plan of a different metal level, and one commenter asked that HHS consider requiring issuers to transfer progress toward accumulators for consumers who change plans through a special enrollment period.

Response: As discussed in the proposed rule, HHS acknowledges these concerns, and will take commenters' suggestions into consideration in our efforts to improve the consumer experience through outreach and education. We also reiterate here that Marketplace issuers have the flexibility to carry over progress towards a previous plan's accumulators for enrollees who change to a different plan mid-year with the same issuer. However, HHS does not have the authority to require that issuers carry over this progress. Issuers must comply with any applicable state requirements regarding accumulators.

Comment: One commenter recommended continuing to apply plan category limitations to enrollees who lose APTC due to a failure to submit documents to confirm their household income, but to provide the additional flexibility to enrollees who lose APTC eligibility for any other reason, citing the difficulties of implementing changes to plan category limitations for different sub-groups of special enrollment period eligible consumers. However, several commenters recommended extending the new flexibility to all enrollees who lose APTC eligibility, including to those who lose APTC due to failure to resolve an inconsistency related to household income. One of these commenters noted that, in addition to a change in household income or a mid-year decision to no longer claim a household member as a tax dependent, enrollees may lose APTC eligibility if a family member is offered employer-sponsored coverage that is considered affordable and the household loses APTC eligibility as a result. Commenters did not express concerns about the possibility, as discussed in the proposed rule, that this policy would allow or encourage individuals to change to a plan of a lower metal level instead of

submitting documentation to resolve an inconsistency to maintain or re-gain their APTC eligibility. However, several commenters expressed concerns about the challenges consumers may face related to submitting documents to resolve an inconsistency and provided recommendations for HHS to improve education and outreach related to document submission. One commenter asked that HHS provide more direct outreach, such as outbound calls and referrals to an enrollment assister, to consumers who fail to resolve inconsistencies and then select lower cost plans to ensure that these enrollees understand their options. Another commenter stated that individuals who lose APTC based on incorrect or out-of-date income information must have a chance to challenge their determination, and suggested that their special enrollment period not expire until 60 days after they receive notice of a final determination of APTC ineligibility. One commenter suggested that in addition to reminding enrollees of the requirement to update their application with changes including to household income, that HHS proactively notify enrollees whose income may have changed based on information from a data source that HHS uses to verify income information.

Response: We agree with commenters that limiting this change in plan category limitations based on reasons why existing enrollees lose APTC eligibility would be burdensome to implement, and may prevent some enrollees from benefitting from the ability to change to a new plan based on a change in their financial situation. We also agree that individuals who lose APTC eligibility due to a family member's offer of employer-sponsored coverage may benefit from being able to change to a plan of a different metal level if it would be difficult for them to afford to enroll in the employer coverage along with their family member. Further, we believe that for most enrollees, the benefit of receiving APTC combined with extensive outreach that HHS conducts for individuals who must submit documentation to confirm their household income sufficiently motivates these individuals to submit necessary documentation. Additionally, we clarify that applicants to Exchanges on the Federal platform who must submit documentation to confirm their household income are first notified of this requirement in the

eligibility notice they receive upon completing their application, and that individuals who do not submit documents, or who submit documents that do not provide enough information to confirm the household income that they attested to on their application, receive a series of reminder notices, calls, and emails.²⁰⁷ We continue to investigate opportunities to improve this outreach.

b. Special Enrollment Periods – Untimely Notice of Triggering Event

We proposed to allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and was otherwise reasonably unaware that a triggering event occurred to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. We also proposed to allow such persons to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event. Finally, we proposed conforming amendments to § 147.104(b)(2)(ii) so that these proposals would also apply to off-Exchange individual health insurance coverage. We are finalizing this policy as proposed.

In accordance with § 155.410(a)(2), an Exchange may allow qualified individuals and enrollees to enroll in or change coverage only during the annual open enrollment period as specified in § 155.410(e), and during special enrollment periods as specified in § 155.420. An Exchange must allow a qualified individual or enrollee to enroll in or change from one qualified health plan to another if one of the triggering events described in § 155.420(d) occurs. Furthermore, under § 155.420(c)(1), a qualified individual or enrollee generally has until 60 days after the date of the triggering event to select a qualified health plan. Section 155.420(c)(2) and (3), provide exceptions to this general rule under which a qualified individual or enrollee may enroll prior to the date of a triggering event. Section 155.420(c)(4) provides a final exception

²⁰⁷ Sample eligibility and reminder notices can be found at <https://marketplace.cms.gov/applications-and-forms/notices>, and an overview of HHS outreach to individuals who must submit documentation to confirm their household income or other information can be found starting on slide 15 of this presentation: <https://marketplace.cms.gov/technical-assistance-resources/complex-cases-data-matching.pdf>.

under which a qualified individual or enrollee may have less than 60 days to enroll. Coverage effective dates are outlined in § 155.420(b) and vary depending on the special enrollment period triggering event, but in all cases are either on or after the date of the triggering event.

Because the time period during which a qualified individual may enroll through a special enrollment period is determined by the triggering event, a qualified individual who does not know the triggering event has occurred may not have sufficient time to enroll in coverage. Generally, the triggering events described in § 155.420(d) and related plan selection timelines under § 155.420(c) are premised on the assumption that an individual will become aware of a triggering event in time to make a plan selection within the time allotted under § 155.420(c). For example, the rules anticipate that qualified individuals or enrollees will receive timely notice of the day they will lose employer-sponsored coverage or the day they will gain a dependent such that 60 days is ample time for the individual to apply for enrollment through an applicable special enrollment period and select a plan. However, our experience operating the Federally-facilitated Exchange has shown that there are circumstances in which an individual reasonably may not be aware of an event that triggers special enrollment period eligibility until after the triggering event has occurred. This change will allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event or was otherwise reasonably unaware that a triggering event occurred, to qualify for an applicable special enrollment period and select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. This proposal will also allow the qualified individual, enrollee, or dependent to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event.

For example, an employer fails to pay its share of premium for an insured employer-sponsored health plan and enters a grace period beginning April 1st, which will expire on May 31st. Because the employer intends to satisfy its premium liability before the end of the grace period, the employer does not notify participants and beneficiaries in the plan of the non-

payment or the risk of termination of its employer-sponsored coverage retroactive to April 1st. The employer is does not timely satisfy the premium debt, and the issuer of the employer-sponsored health coverage terminates coverage for the participants and beneficiaries retroactively to April 1st. Neither the employer nor the issuer of the employer-sponsored health plan notify the participants and beneficiaries of the beginning of the grace period or that coverage would be terminated as of April 1st. On July 10th, the participants and beneficiaries first receive notice from the issuer that their coverage terminated as of April 1st. In accordance with the circumstances described in 26 CFR 54.9801-6(a)(3)(i), due to the employer's failure to timely pay premiums, the participants and beneficiaries of the employer-sponsored health plan lost eligibility for the coverage and are eligible for the special enrollment period provided in § 155.420(d)(1)(i). Per paragraph (d)(1)(i), the triggering event for special enrollment periods due to loss of minimum essential coverage is the last day the consumer would have coverage under his or her previous plan or coverage. But in this scenario, affected participants and beneficiaries, through no fault of their own, were not aware of their loss of minimum essential coverage until more than 60 days following the last day they had coverage. Thus, without the measure we proposed here, the participants and beneficiaries in this example would not be able to use the special enrollment period at paragraph (d)(1)(i), because more than 60 days had passed since the relevant triggering event without their having selected a new plan. Some participants and beneficiaries of employer-sponsored health plans are experiencing similar circumstances during the COVID-19 public health emergency and sought or seek individual health insurance coverage through the FFEs, exposing a perceived gap in current special enrollment period rules.

Another circumstance in which an individual may not be aware that a triggering event occurred involves technical errors that block an individual from enrolling in coverage through an Exchange. Section 155.420(d)(4) specifies that an individual is eligible for a special enrollment period if, among other things, their erroneous non-enrollment in a qualified health plan was due to an error on the part of the Exchange or one of its agents. In this case, the error itself is the

triggering event, and the date it occurs serves as the beginning of the special enrollment period. However, as in the case of the loss of employer-sponsored coverage discussed above, an individual may not be aware that an error has occurred. In some cases, the Exchange may not be aware that a technical error has occurred which prevented individuals from enrolling until a subsequent investigation is conducted. This process may take several weeks, during which time an impacted individual may not be aware that they were unable to enroll due to an error and therefore qualify for a special enrollment period. There may even be cases in which an Exchange does not identify the issue and the impacted population and notify them until more than 60 days after the triggering event occurred.

Therefore we proposed to amend § 155.420 by adding paragraph (c)(5) to specifically provide that if a qualified individual, enrollee, or dependent does not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event occurred, the Exchange must allow them to select a new plan within 60 days of the date that they knew, or reasonably should have known, of the occurrence of the triggering event. Additionally, we proposed to add paragraph (b)(5) to clarify that when a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period, the Exchange must allow the such persons the option to choose the earliest coverage effective date for the triggering event under paragraph (b) that would have been available if they had received timely notice of the triggering event. In addition, we proposed that the Exchange must also provide the qualified individual, enrollee or dependent the option to choose the effective date that would otherwise be available under the other provisions in paragraph (b).

Lastly, we proposed a conforming edit to § 147.104(b)(2) that would incorporate these amendments by reference in the regulations governing limited open enrollment periods for off-Exchange coverage, so that these proposed special enrollment rules would apply to issuers of non-grandfathered individual health insurance, both on and off-Exchange. We also separately

proposed a change to § 147.104(b)(2)(ii) to clarify how the special enrollment period in § 155.420(d)(4) applies off-Exchange. This change is discussed in further detail in the preamble to part 147.

We sought comment on these proposals.

We received public comments on the proposed updates to Special Enrollment Periods – Untimely Notice of Triggering Event. The following is a summary of the comments we received and our responses.

Comment: All commenters, except for one, expressed support for the proposal, explaining that it provides flexibility for situations in which a consumer was reasonably unaware that a special enrollment period triggering event occurred. Several commenters stated that this proposal is especially appropriate given the ongoing economic downturn and COVID-19 pandemic, which will increase the number of consumers without coverage. Others stated that it will help promote continuity of coverage, and reduce the uninsured population. Several commenters stated that the proposal would help reduce challenges with special enrollment period enrollment, such as a lack of clear messaging and insufficient time to select an appropriate plan. A few commenter stated that the proposal will allow more people to enroll in special enrollment periods.

Response: We agree that this proposal will have a positive impact by providing consumers who were reasonably unaware of a special enrollment period triggering event with an opportunity to enroll, as well as the other benefits noted by commenters. As a result, we are finalizing this policy as proposed.

Comment: One commenter opposed the proposal, which they characterized as establishing a new special enrollment period, absent a requirement that enrollees provide evidence of the lack of timely notice of a special enrollment period triggering event. This commenter expressed concern that there are insufficient mechanisms currently to verify the lack

of timely notice, and that the proposal would create an open-ended, year-round opportunity to enroll in coverage, thus increasing the likelihood of adverse selection.

Response: We clarify that the proposed rule does not establish new circumstances through which a special enrollment period would be available, but simply provides additional flexibility regarding when existing special enrollment periods can be accessed in the relatively rare circumstances in which a consumer was reasonably unaware that a triggering event occurred. The proposed rule thus would not create an open-ended special enrollment period through which anyone could enroll, and only consumers who attest to being reasonably unaware that they experienced a special enrollment period triggering event would be eligible to avail themselves of this opportunity. We also note that, for Exchanges on the Federal platform, some enrollments under this authority will be subject to special enrollment period verification, though there may be others that require caseworker review. Finally, we note that we will continue to monitor the implementation of this provision and propose additional policy and operational updates, including expanding the use of special enrollment period verification, if necessary.

Comment: A few commenters expressed support for the proposed rule, but requested that HHS limit enrollments under this authority to prospective coverage effective dates, and not allow retroactive coverage effective dates. These commenters stated that if retroactive coverage effective dates are permitted, the risk of adverse selection and higher premiums for all enrollees will increase. One of these commenters additionally stated that allowing retroactive coverage effective dates makes it more difficult for issuers to contest improper claims. Another commenter expressed concern regarding the burden of providing retroactive coverage for State Exchanges, and about whether consumers enrolling with a retroactive coverage effective date would be required to pay all past due premiums at once, and whether this would lead to a gap in coverage if they were unable to do so. This commenter requested that we clarify the options available to consumers in this scenario if they are unable to pay all past due premiums. Several other commenters expressed support for providing consumers with the earliest effective date that

would otherwise have been available to them had they been aware of the triggering event, stating that this will help maintain continuity of coverage.

Response: While we acknowledge the concerns raised by commenters related to potential adverse selection and increased premiums, we believe this risk to be low due to the rare circumstances in which a consumer would not be notified or become reasonably aware of a triggering event until after it has occurred. We further anticipate that instances of consumers experiencing significant delays in notification or awareness of a triggering event are even rarer, thus minimizing the overall risk of adverse selection and burden on State Exchanges to implement. Regarding the concern of one commenter that consumers may not be able to afford to pay all past due premiums if they choose a retroactive coverage effective date, we note that consumers have the option of choosing a prospective coverage effective date instead.

Comment: Several commenters expressed support for the proposal, but requested that, to prevent abuse by consumers and agents and brokers and to avoid establishing an open-ended opportunity for enrollment, HHS narrow the scope of the proposal to only cover certain special enrollment periods. A few of these commenters requested that HHS limit the proposal to scenarios in which an individual with employer-sponsored coverage was not informed by their employer of the loss of coverage, such as the first example discussed in the preamble of the proposed rule. These commenters also stated that HHS already has the authority to provide flexible effective dates for special enrollment periods due to error of the Exchange, and so the flexibility provided by the proposal rule is unnecessary for these situations. One commenter requested that HHS limit the proposal to situations in which an individual with employer-sponsored coverage was not informed by their employer of the loss of coverage, plus scenarios in which an individual is unaware of the date they gained a dependent. Another commenter requested that HHS apply parameters to the proposal, such as limiting the duration to a specific time period such as a public health emergency, or limiting it to the examples discussed in the preamble of the proposed rule.

Response: Although we appreciate the concerns raised by commenters, we are finalizing the rule as proposed. Although some commenters state that HHS already has authority under the exceptional circumstances or error of Exchange special enrollment periods to provide enrollees with flexible effective dates, we note that there are other special enrollment period triggering events, not explicitly discussed as examples in the proposed rule, of which an enrollee may be reasonably unaware, and for which there is no current authority to provide for an enrollment outside the normal window of availability. Furthermore, the exceptional circumstances special enrollment period authority noted by commenters is subject to each Exchange's reasonable interpretation regarding what qualifies as "exceptional." The proposed rule, by contrast, establishes a clear mandate to allow enrollees who were reasonably unaware that a special enrollment period triggering event occurred to use the date they became aware as the triggering event, which will provide transparency and consistency in implementation of this rule across Exchanges and for individual health insurance coverage. Finally, we note that, because the proposal was intended to establish a way to make whole consumers who have been harmed through no fault of their own, limiting its availability to certain special enrollment period types would be inconsistent with the purpose of this proposed rule.

Comment: A few commenters expressed support for the proposal, but requested that enrollments under this authority be subject to document-based verification to prevent abuse by consumers and agents and brokers.

Response: On Exchanges on the Federal platform, some enrollments under this authority will be subject to special enrollment period verification, though others will likely require caseworker review. Because many State Exchanges and off-Exchange issuers already conduct special enrollment period verification, HHS did not set explicit requirements for State Exchanges or off-Exchange issuers regarding special enrollment period verification for enrollments under this provision. Therefore, we cannot say with certainty whether these entities would subject such enrollments to verification.

Comment: Two commenters requested that HHS implement this proposal sooner than the scheduled January 1, 2022 implementation date.

Response: We note that this provision will become effective on the effective date of this rule, and thus the proposal will be implemented sooner than January 1, 2022.

Comment: Two commenters, noting the difficulties that some consumers face in understanding special enrollment period eligibility and gathering supporting documentation within the 60-day window, expressed support for providing consumers with a window of 60 days from the date they are notified of special enrollment period eligibility to enroll.

Response: Although we appreciate the concerns raised regarding the ability of consumers to understand and comply with the process for enrolling in a special enrollment period within the 60-day window, establishing a policy of providing consumers with a 60-day window from the date they become aware of special enrollment period eligibility would be inconsistent with existing rules for special enrollment period eligibility. Currently, eligibility for special enrollment periods on Exchanges on the Federal platform and many State Exchanges is based on the occurrence of a triggering event, such as a loss of minimum essential coverage, rather than the date an enrollee becomes aware of their special enrollment period eligibility. Therefore, to maintain consistency in special enrollment period operations across these Exchanges, we believe it is appropriate to establish the date an enrollee becomes aware of the occurrence of a triggering event as the triggering event, rather than the date they become aware of their eligibility for a special enrollment period.

Comment: One commenter requested that HHS broadly interpret the phrase “reasonably unaware” in the regulation text for this proposed rule, and stated that HHS should not second-guess a consumer’s statement that they were unaware of a special enrollment period triggering event. Another commenter requested that HHS explain the meaning of this phrase, noting that if interpretation is left up to those providing enrollment assistance, it would be burdensome for

State Exchange operations and require processes to individually advise consumers on the date that they should have known about a special enrollment period triggering event.

Response: HHS appreciates the concerns raised regarding how the phrase “reasonably unaware” in the regulation text will be interpreted. Although we do not provide an exact definition of this phrase, we note the two examples included in the preamble of the proposed rule, which describe scenarios in which an individual was reasonably unaware that a special enrollment period triggering event had occurred. In addition, to provide further clarity we include the following example, which illustrates a situation in which a consumer would not have been reasonably unaware that a special enrollment period triggering event occurred. The examples in the preamble to the proposed rule make clear that interpretation of the phrase “reasonably unaware” is not entirely up to individuals providing enrollment assistance. In addition, we also note that the legal standard of what constitutes a reasonable person provides objectivity to whether a consumer in this scenario would be reasonably unaware.

Example: A consumer visits HealthCare.gov on December 1 (during the annual open enrollment period), and while filling out an application, is informed that they may be eligible for Medicaid. The consumer then fills out an application with their state Medicaid office. On February 3 of the following year, they receive a letter from the state Medicaid office informing them that they are ineligible for Medicaid, but fail to open the letter. On April 1 the consumer finds the unopened letter and reads it, and then attempts to enroll in a qualified health plan on HealthCare.gov, attesting to eligibility for the Medicaid denial special enrollment period based on the February 3 letter informing them of their ineligibility for Medicaid. The consumer failed to enroll in the special enrollment period they would have been eligible for under 45 CFR 155.420(d)(11)(i) within the allotted 60-day window because they were unaware of the triggering event, in this case the determination of ineligibility for Medicaid on February 3, when it occurred. However, they are not eligible to avail themselves of the provision in § 155.420(c)(5) because, had they opened the letter informing them of their ineligibility for Medicaid within a

reasonable period of time after receiving it, they would have been made aware of the occurrence of a special enrollment period triggering event, and thus they were not reasonably unaware that one had occurred.

Comment: One commenter requested that HHS discuss whether consumers will be able to access this special enrollment period through HealthCare.gov, which they note would be preferable to enrollments through the call center.

Response: Although enrollees under this authority may be able to enroll using the application on HealthCare.gov, there are likely to be cases in which enrollees must access the special enrollment period they are eligible for through the Marketplace Call Center or a caseworker.

Comment: One commenter expressed support for the proposal, and also asked that the Department of Labor consider implementing this proposal for the group insurance market as well.

Response: HHS does not have the authority to change Department of Labor regulations, and so we are unable to finalize such changes. We note that the Department of Labor regulates group health plans under the Employee Retirement Income Security Act of 1974 (ERISA), and that HHS regulates the group health insurance market. We did not propose to apply this provision to the group health insurance market, and will therefore not finalize such a provision here. However, we will continue to monitor this issue and propose changes related to HHS regulations for the group health insurance market in the future, if appropriate.

Comment: One commenter expressed support for the proposal, but also expressed concern regarding the potential for unintentional loss of dental coverage as a result of changes in other health coverage, for example if a consumer enrolls in both a qualified health plan and stand-alone dental plan, but due to an error of the Exchange was prevented from enrolling in the stand-alone dental plan. They request that HHS allow consumers enrolling under the authority in the proposed rule to also select a dental plan, and suggest that this could be accomplished by

removing the link between qualified health plans and stand-alone dental plans on the Federally-facilitated Exchanges.

Response: We appreciate the concern raised regarding the potential impact of the proposed rule on dental insurance, and note that nothing would prevent a consumer from enrolling in a stand-alone dental plan under the authority in the proposed rule. For this reason we believe that removing the link between qualified health plans and stand-alone dental plans on the Federally-facilitated Exchanges is not necessary, but we will continue to monitor this issue and propose changes in the future if necessary.

Following review of the comments, we are finalizing this policy as proposed.

c. Cessation of Employer Contributions or Government Subsidies to COBRA as Special Enrollment Period Trigger

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA)²⁰⁸ (Pub. L. 99-272, April 7, 1986) provides for a temporary continuation of group health coverage following, among other circumstances, employees' separation from an employer, for reasons other than gross misconduct, in instances where such separation would otherwise cause termination of coverage. Although employees who elect to receive COBRA continuation coverage may be required by their former employer to pay their former employer's share of the premiums as well as their own,²⁰⁹ some employers pay all or a portion of their former employee's premium for part or all of the COBRA coverage period. In addition, government entities will sometimes subsidize COBRA continuation coverage premiums, whether as a direct payment or via a third party such as an employer.

In accordance with the policy currently in place on the Exchanges on the Federal platform, we proposed to amend § 155.420(d)(1) to state that the complete cessation of employer

²⁰⁸ <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf>.

²⁰⁹ Individuals electing COBRA may also be required by their former employer to pay a 2 percent administrative fee. See <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf>.

contributions for COBRA continuation coverage serves as a triggering event for special enrollment period eligibility. We are instead finalizing this policy under new paragraph (d)(15), rather than in paragraph (d)(1)(v) as we proposed. We are also finalizing text providing that the special enrollment period will be available when subsidies from a government entity completely cease.²¹⁰ The triggering event for this special enrollment period is the last day of the period for which COBRA continuation coverage was paid for or subsidized, in whole or in part, by an employer or a government entity.

Exchange regulations at § 155.420(d)(1)(i) provide that when a qualified individual or his or her dependent loses minimum essential coverage as defined by § 155.20, they gain eligibility for a special enrollment period, during which they can enroll in a qualified health plan.

Paragraph (e) of § 155.420 states that loss of minimum essential coverage as described in paragraph (d)(1) includes the circumstances listed at 26 CFR 54.9801-6(a)(3)(i) through (iii).

These provisions describe conditions under which someone may qualify for a special enrollment period for group health plan coverage, including paragraphs (a)(3)(i), “Loss of eligibility for coverage,” and (a)(3)(iii), “exhaustion of COBRA continuation coverage.” Exhaustion of COBRA coverage is defined in 26 CFR 54.9801-2(4) as cessation of COBRA coverage for reasons other than failure of the individual to timely pay premiums, and includes coverage ceasing due to “failure of the employer or other responsible entity to remit premiums on a timely basis.”

In implementing special enrollment periods for Exchanges on the Federal platform, HHS has provided a loss of minimum essential coverage special enrollment period under § 155.420(d)(1)(i) for individuals whose COBRA costs change because their former employer completely ceases contributions and as a result they must pay the full cost of premiums.

²¹⁰ Because employers are not required to charge a 2 percent administrative fee to individuals who elect COBRA, we do not include this fee in the definition of “employer contributions.” For purposes of this section, if an individual enrolled in COBRA continuation coverage without employer contributions (so that the individual was responsible for 100 percent of the premiums) was not required to pay a 2 percent administrative fee, this would not be considered an employer contribution for the purposes of the proposed special enrollment period.

However, loss of coverage based on complete cessation of employer contributions for COBRA coverage might not have been treated as a triggering event by issuers of individual health insurance coverage off-Exchange or by State Exchanges. HHS believes it is important that individuals have access to a special enrollment period in the individual market when their former employer or a government entity completely ceases contributions or subsidies to COBRA continuation coverage, because the cost of COBRA continuation coverage premiums can be substantial, rendering this type of coverage unaffordable for many people to whom it would be available.²¹¹ Ensuring that this special enrollment period is widely available will help promote continuity of coverage for those who cannot maintain their COBRA continuation coverage without contributions or subsidies from their employer or a government entity. HHS therefore proposed to make this special enrollment period available throughout the individual market.

We proposed to amend § 155.420 by adding paragraph (d)(1)(v) stating that a special enrollment period is triggered when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, and the employer completely ceases its contributions, with the triggering event being the last day of the period for which COBRA continuation coverage is paid for, in whole or in part, by the employer. We are instead finalizing proposed paragraph (d)(1)(v) as (d)(15), and in addition we are also finalizing a change to (e)(1) to explicitly exclude (d)(15). In the preamble to the proposed rule, we clarified that the triggering event for this special enrollment period would be based on loss of employer contributions to COBRA continuation coverage, rather than the loss of coverage itself. Thus, eligibility for this special enrollment period does not depend on loss of COBRA coverage, as illustrated by the examples we included. However, proposed paragraph (d)(1)(v), like the rest of paragraph (d)(1), would have been subject to paragraph (e), which states that loss of coverage excludes voluntary termination of coverage, and (e)(1), which states that loss of coverage does not include failure to pay premiums on a timely basis, including COBRA

²¹¹ <https://www.kff.org/private-insurance/issue-brief/key-issues-related-to-cobra-subsidies/>.

premiums. Although new paragraph (d)(15) will not be subject to the provisions in (e), we are concerned that stakeholders may still be uncertain about whether individuals who voluntarily end COBRA continuation coverage or have such coverage terminated following a loss of employer contributions or government subsidies would still be eligible for this special enrollment period, given the limitations imposed by paragraph (e)(1). Therefore, we are finalizing proposed paragraph (d)(1)(v) as (d)(15), which is not subject to paragraph (e). In addition, we are also finalizing a change to paragraph (e)(1) to explicitly exclude the special enrollment period trigger in paragraph (d)(15), making clear that individuals who voluntarily end COBRA continuation coverage or have such coverage terminated following a loss of employer contributions or government subsidies are still eligible for this special enrollment period, and to use the term “COBRA continuation coverage” consistently.

Similar to the special enrollment period for termination of employer contributions to employer-sponsored coverage at 26 CFR 54.9801-6(a)(3)(ii), we proposed that the triggering event is the last day of the period for which COBRA continuation coverage is paid for, in part or in full, by an employer. Furthermore, we proposed to clarify that complete cessation of employer contributions toward employer-sponsored continuation coverage under state mini-COBRA laws²¹² also serves as a special enrollment period triggering event. These changes would make explicit HHS’s current policy with regard to the Exchanges on the Federal platform, and would ensure that individual health insurance coverage sold off-Exchange and through State Exchanges align with it. In addition, establishing paragraph (d)(15) to explicitly include complete cessation of employer contributions and government subsidies to COBRA continuation coverage as a special enrollment period triggering event will mitigate confusion among employers and employees, as well as other stakeholders, about their options regarding COBRA continuation coverage and special enrollment period eligibility.

²¹² <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf>.

Similar to other special enrollment periods based on loss of minimum essential coverage, in the Exchanges, this special enrollment period would be subject to the provisions in paragraph (a)(4)(iii)(B) and (C), which allow dependents and non-dependent qualified individuals who qualify for a special enrollment period to be added to the QHP of a household member who is already enrolled in Exchange coverage, or to enroll separately in a plan of any metal level. We also proposed that the Exchange must provide the qualified individual, enrollee, or dependent the effective date that would otherwise be available pursuant to the other provisions at paragraph (b)(2)(iv). To ensure that this provision applies to new paragraph (d)(15), we are also finalizing changes to paragraph (b)(2)(iv) to include paragraph (d)(15) in the list of special enrollment periods that are subject to the paragraph. In addition, we proposed that an individual eligible for this special enrollment period would have 60 days before or after the triggering event (in this case, the last day for which the qualified individual or dependent has COBRA continuation coverage to which an employer or governmental entity is contributing) to select a qualified health plan. Therefore we are also finalizing changes to paragraph (c)(2) to include new paragraph (d)(15). We also proposed that this special enrollment period, which would be incorporated by reference in the guaranteed availability regulations at § 147.104(b)(2), apply with respect to individual health insurance coverage offered through and outside of an Exchange.

To help clarify the circumstances that would trigger the proposed special enrollment period, we included the following example:

Example 1: An individual is laid off from a job on June 1, and 5 days later enrolls in COBRA continuation coverage for which the employer pays 100 percent of the premiums (the employer does not require payment of a 2 percent administrative fee). On September 3 of that year, the employer informs the individual that it is completely terminating contributions to the individual's COBRA continuation coverage as of September 30, and beginning on October 1, the individual will be responsible for 100 percent of the COBRA continuation coverage premiums. As a result, the individual decides to end COBRA coverage effective October 1. Because

September 30 is the last day for which the individual had COBRA continuation coverage for which the employer was contributing, the individual has 60 days before and after September 30 (in this case, through November 29) to select an individual market plan through a special enrollment period.

In addition to this proposal, HHS also considered addressing situations in which an employer reduces, but does not completely cease, its contributions for COBRA continuation coverage. In particular, we considered adding to proposed paragraph § 155.420(d)(1)(v) a provision that a reduction of employer contributions to COBRA continuation coverage would also serve as a special enrollment period trigger. We also sought comment on whether HHS should also adopt a threshold for the level of reduction of employer contributions to COBRA continuation coverage that would be necessary to trigger the special enrollment period. However, we are not finalizing this policy.

Lastly, we note that in addition to employer contributions to COBRA continuation coverage, COBRA coverage is sometimes subsidized by government entities as well, either directly or through a third party such as an employer.²¹³ As noted in the preamble to the proposed rule and earlier in this preamble, HHS believes it is important that individuals have access to a special enrollment period in the individual market when contributions to COBRA continuation coverage cease, because the cost of COBRA continuation coverage premiums are substantial, rendering this type of coverage unaffordable for many people to whom it would be available. This issue applies equally to cessation of employer contributions and cessation of government subsidies. As with employer contributions to COBRA continuation coverage, providing individuals with a special enrollment period when subsidies from a government entity completely cease will promote continuity of coverage among those who could not maintain their coverage without such subsidies. Therefore, we are also finalizing in new paragraph §

²¹³ For example, the American Rescue Plan Act of 2021 provides individuals enrolled in COBRA continuation coverage with subsidies that cover 100 percent of premiums through September 30, 2021.

155.420(d)(15) the provision that a special enrollment period is triggered when subsidies from a governmental entity to COBRA continuation coverage, whether paid directly or through a third party, completely cease. The triggering event is the last day of the period for which COBRA continuation coverage is paid for or subsidized, in whole or in part, by an employer or government entity.

We also provide the following example to illustrate how the special enrollment period would work with regard to government subsidies of COBRA continuation coverage premiums.

Example 2: Same scenario as in the first example, except that, as under the American Rescue Plan Act of 2021, the COBRA continuation coverage the individual is receiving is fully subsidized by the federal government, so that the individual does not have to pay any portion of the COBRA premium. The federal subsidy is set to expire on September 30, and as a result, beginning October 1 the individual will be responsible for the full amount of the COBRA continuation coverage premiums. The individual decides to end their coverage effective October 1, and as a result will have 60 days before and after the last day for which they have COBRA continuation coverage with federal subsidies (in this case, through November 29) to enroll in individual health insurance coverage through a special enrollment period.

We received public comments on the proposed updates to cessation of employer contributions to COBRA as special enrollment period trigger. The following is a summary of the comments we received and our responses.

Comment: No commenters opposed this proposal, and many supported it, explaining that codifying this special enrollment period in regulation would enhance transparency regarding the availability of this special enrollment period on Exchanges on the Federal platform, and mitigate confusion among employers and employees about their options regarding COBRA continuation coverage and special enrollment period eligibility. Several commenters agreed that, since consumers who lose employer contributions to COBRA continuation coverage face a financial calculation that is different than the one they made when originally enrolling in COBRA

coverage, a special enrollment period is appropriate. Several others stated that this proposal is especially appropriate given the ongoing economic downturn and COVID-19 pandemic. Other commenters stated that this proposal will help promote continuity of coverage, and noted that this is especially important given that individuals with COBRA are more likely to have higher medical expenses. A few commenters stated that this special enrollment period is especially appropriate given the limited options faced by consumers who choose to maintain their COBRA continuation coverage once employer contributions end. Another agreed that it is important to provide flexibility for consumers who are in a situation over which they have no control. One commenter stated that this special enrollment period is especially important for individuals with chronic health conditions, such as HIV. Another commenter noted that special enrollment periods such as this provide a critical safety net for consumers outside of the annual open enrollment period. Another stated that the proposed rule would likely encourage employers to assist laid-off workers with contributions to COBRA. Finally, one commenter stated that the proposal will have the beneficial effect of allowing more individuals to enroll through special enrollment periods.

Response: We agree that the proposed changes would enhance transparency and mitigate confusion regarding an existing policy of the Exchanges on the Federal platform and options for consumers regarding special enrollment period eligibility, in addition to the other benefits noted by commenters. Accordingly, we are finalizing this policy as proposed (but with the additional provision regarding government subsidies).

Comment: Several commenters expressed support for the proposal, and in addition supported designating partial reductions in employer contributions to COBRA continuation coverage as a special enrollment period triggering event. These commenters noted that due to the high cost of COBRA continuation coverage, even a partial reduction in employer contributions could make such coverage unaffordable for many consumers. In addition, they noted that including partial reduction of employer contributions as a special enrollment period trigger

would promote access to health insurance by providing another pathway by which individuals can enroll in coverage. Several commenters also expressed support for establishing a threshold amount by which employer contributions must decrease in order to trigger special enrollment period eligibility. A few of these commenters expressed support for defining a threshold based on affordability to the consumer. One commenter suggested using a threshold of 10 percent as an approximation of a material reduction in employer contributions. Another commenter noted the IRS' threshold for evaluating affordability of employer-sponsored coverage of 9.83 percent, which they are concerned may be too high for the purposes of COBRA coverage given the financial challenges faced by consumers following a loss of employment. Finally, a few other commenters opposed establishing a threshold, arguing that it would be unnecessarily burdensome to consumers and noting that even partial reductions can render COBRA coverage unaffordable. These commenters instead supported designating a reduction in employer contributions to COBRA of any amount as a special enrollment period triggering event.

Response: HHS recognizes the concerns raised by commenters regarding the high cost of COBRA continuation coverage, even with partial employer contributions. However, because the number of COBRA enrollees with employer subsidies is already low relative to the rest of the individual insurance market,²¹⁴ we believe it is likely that situations in which employer contributions to COBRA continuation coverage are reduced significantly enough to render such coverage unaffordable affect only a very small number of consumers. Accordingly, we are not finalizing reduction of employer contributions to COBRA continuation coverage as a special enrollment period trigger, but will continue to monitor this situation in the future.

Comment: Two commenters requested that HHS implement this special enrollment period sooner than the scheduled 2022 implementation date.

Response: We note that the requirement to provide this special enrollment period goes into effect on the effective date of this rule, which is sooner than the 2022 implementation date.

²¹⁴ <https://www.cbo.gov/system/files/2021-02/hEdandLaborreconciliationestimate.pdf>.

Comment: Two commenters expressed support for applying this special enrollment period to off-Exchange individual health insurance coverage and on State Exchanges. One of these commenters noted that establishing more consistent special enrollment period rules on and off-Exchange would help reduce the on-Exchange disadvantage.

Response: We agree that it is appropriate to apply this special enrollment period market-wide to individual health insurance coverage, including for coverage offered off-Exchange and on State Exchanges, and thus we are finalizing this policy as proposed (but with the additional provision regarding government subsidies).

Comment: Two commenters expressed support for the proposal, and also suggested that HHS establish a special enrollment period for individuals, and their dependents, who voluntarily terminate their COBRA coverage, regardless of whether they are receiving employer contributions. These commenters also added that not doing so would penalize an enrollee who chooses to enroll in COBRA in an effort to maintain their coverage. One of the commenters suggested this policy as a way of expanding the number of ways in which consumers can enroll in Exchange coverage.

Response: Although we appreciate the concerns raised regarding the availability of a special enrollment period for individuals who are not receiving employer contributions to COBRA coverage, we do not believe that establishing such a special enrollment period is necessary. In general, when a consumer has the opportunity to elect COBRA continuation coverage, they also will have the opportunity to enroll in a qualified health plan on the Exchanges on the Federal platform or a State Exchange as well as off-Exchange, as they will likely be eligible for a loss of minimum essential coverage special enrollment period. In addition, special enrollment periods are generally based on triggering events that do not include voluntary termination of coverage, which would introduce concerns regarding adverse selection in the individual market.

Comment: One commenter expressed support for the proposal, but requested that HHS implement stronger verification mechanisms, such as provision of a letter indicating the termination of employer contributions to COBRA. This commenter also noted that verification would benefit the enrollee by ensuring they do not pay out-of-pocket for coverage already covered through employer contributions.

Response: This special enrollment period has been subject to special enrollment period verification on Exchanges on the Federal platform, subject to the loss of minimum essential coverage special enrollment period attestation. Similarly, many State Exchanges already conduct special enrollment period verification. With respect to off-Exchange enrollments using special enrollment periods, subject to applicable state law, issuers may implement reasonable procedures to verify eligibility for special enrollment periods, and because these Exchanges and issuers are able to determine for themselves whether verification is needed, we do not believe it is necessary to require them to establish specific verification procedures for this special enrollment period.

Comment: One commenter requested that HHS discuss whether consumers will be able to access this special enrollment period through HealthCare.gov, which they note would be preferable to enrollments through the call center.

Response: This special enrollment period has been, and will continue to be, available to enrollees on Exchanges on the Federal platform through the application on HealthCare.gov.

Comment: One commenter expressed support for the proposal, and requested that HHS allow enrollees through this special enrollment period to select a plan of any metal level when they enroll.

Response: Enrollments through this special enrollment period on Exchanges on the Federal platform and State Exchanges are subject to plan category limitations, including metal level restrictions, under 45 CFR 155.420(a)(4)(iii). We note, however, that because plan category limitations apply only to current Exchange enrollees, consumers enrolling through this special enrollment period on an Exchange would only be subject to them in situations where they were

added to an existing policy. Although we appreciate the concern raised regarding allowing enrollees to select a plan of any metal level, because we did not propose to exempt enrollments through this special enrollment period from plan category limitations in the proposed rule, we are not finalizing such a change here. However, we will continue to monitor this issue in the future. We also note that enrollments in off-Exchange coverage are not subject to plan category limitations, and thus consumers enrolling through this special enrollment period off-Exchange could select a plan of any metal level.

Comment: One commenter requested that HHS provide resources to make the public aware of the opportunity to enroll during a special enrollment period when employer contributions to COBRA coverage cease.

Response: HHS will leverage existing HealthCare.gov content to ensure that enrollees are aware of their options regarding cessation of employer contributions to COBRA coverage and special enrollment period eligibility.

Comment: One commenter requested that HHS also establish a special enrollment period for enrollees who experience a decrease in APTC that renders coverage unaffordable to them.

Response: We appreciate the concerns raised regarding individuals who experience a decrease in APTC that renders their coverage unaffordable. As described earlier in this section of the preamble, in this rule we decided not to finalize a special enrollment period where employer contributions to or government subsidies of COBRA coverage are reduced but do not completely cease. We will continue to monitor this situation in the future, and will consider it for future rulemaking.

As a result of the comments, we are finalizing this policy as proposed, except that we are finalizing proposed paragraph (d)(1)(v) as paragraph (d)(15), with the additional provision that cessation of government subsidies to COBRA continuation coverage will also result in a special enrollment period trigger, and with other conforming changes discussed in this section of the

preamble. However, we are not finalizing the proposal to include reduction of employer contributions to COBRA continuation coverage as a special enrollment period trigger.

d. Special Enrollment Period Verification

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all FFEs and SBE-FPs and encouraged states to do the same in State Exchanges.

Since 2017, Exchanges on the Federal platform have implemented pre-enrollment special enrollment period verification for special enrollment period types commonly used by consumers to enroll in coverage. Consumers who are not already enrolled through the Exchange and who apply for coverage through a special enrollment period type that requires pre-enrollment verification by the Exchange must have their eligibility electronically verified using available data sources, or they must submit supporting documentation to verify their eligibility for the special enrollment period before their enrollment can become effective. As stated in the HHS Marketplace Stabilization Rule, special enrollment period verification is only conducted for new enrollees due to the potential for additional burden on issuers and confusion for consumers if required for existing enrollees.

In implementing pre-enrollment verifications for special enrollment periods in the Market Stabilization Rule, HHS did not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications, in order to allow State Exchanges with flexibility to adopt policies that fit the needs of their state.²¹⁵ Currently, all State Exchanges now conduct either pre- or post-enrollment verification of at least one special enrollment type.

We proposed to amend § 155.420 to add paragraph (f) to require all Exchanges to conduct eligibility verification for special enrollment periods. Specifically, we proposed to require that Exchanges conduct special enrollment period verification for at least 75 percent of

²¹⁵ 82 FR at 18356.

new enrollments through special enrollment periods for consumers not already enrolled in coverage through the applicable Exchange.

We also proposed that under § 155.315(h), State Exchanges would have the flexibility to propose alternative methods for conducting required verifications to determine eligibility for enrollment in a QHP under subpart D, and to allow State Exchanges to request HHS approval for use of alternative processes for verifying eligibility for special enrollment periods as part of determining eligibility for special enrollment periods under § 155.305(b).

We sought comment on these proposals. With respect to Special Enrollment Period Verification, we sought comment from States about the 75 percent verification threshold and whether it should be based on past year or current year special enrollment period enrollments, understanding that unforeseen events may occur that may drive up or down enrollments from year-to-year.

We received public comments on the proposed updates to require Exchanges to conduct Special Enrollment Period verification. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed policy. However, the majority of commenters opposed the policy due to the administrative burden to consumers and the financial and administrative burden on State Exchanges. Several commenters stated that State Exchanges have the best understanding of their needs around special enrollment period verification and are best able to determine their SEP verification strategy and thresholds. Several commenters did not think that CMS provided justification for the 75 percent threshold or the policy change by citing evidence of a negative risk pool impact, abuse of SEPs, or ongoing problems with Exchanges' current practices. A few commenters expressed concern that the proposal could negatively affect the risk pool by deterring younger and healthier enrollees from completing enrollment. One commenter asked for further guidance on the flexibility for states and what constitutes alternative means. One commenter suggested to waive this requirement until

additional research can be conducted to ensure that the policy does not create an undue burden on individuals. One commenter noted that stricter SEP enforcement mechanisms have the potential to improve the risk profile, but any requirements regarding SEP enrollment should not be onerous enough to reduce participation among those legitimately eligible.

Response: We agree with commenters who expressed concerns about imposing administrative or financial burden on State Exchanges or administrative burden on consumers at this time with additional new requirements. We estimate that there are only four State Exchanges that conduct more limited special enrollment period verification than the Exchanges on the Federal platform, but these State Exchanges still conduct some form of special enrollment period verification. These also include the 3 smallest State Exchanges in terms of numbers enrolled and issuer participation. These State Exchanges have reported to HHS that, based on regular communications they have with their issuers about special enrollment periods, they do not have evidence to suggest there is misuse of special enrollment periods occurring.

Following review of the comments, we are not finalizing this proposal.

9. Required Contribution Percentage (§ 155.605(d)(2))

HHS calculates the required contribution percentage for each benefit year using the most recent projections and estimates of premium growth and income growth over the period from 2013 to the preceding calendar year. Accordingly, we proposed the required contribution percentage for the 2022 benefit year, calculated using income and premium growth data for the 2013 and 2021 calendar years.

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 would 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 reduced 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 would 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 are finalizing as the measure for premium growth the 2022 premium adjustment percentage of 1.3760126457 (or an increase of about 37.6 percent over the period from 2013 to 2021). This reflects an increase of about 1.6 percent over the 2021 premium adjustment percentage ($1.3760126457/1.3542376277$).

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we would use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice and proposed for use in the 2022 Payment Notice, the rate of income growth for 2022 is the percentage (if any) by which the NHEA Projections 2019-2028 value for per capita PI for the preceding calendar year (\$61,156 for 2021) exceeds the NHEA Projections 2019-2028 value for per capita PI for 2013 (\$44,948), carried out to ten significant digits. The ratio of per capita PI for 2021 over the per capita PI for 2013 is estimated to be 1.3605944647 (that is, per capita income growth of about 36.1. percent).²¹⁶ This rate of income growth between

²¹⁶ The 2013 and 2021 per capita personal income figures used for this calculation reflect the NHE Projections 2019-2028, published on March 24, 2020. 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 2019-2028

2013 and 2021 reflects an increase of approximately 3.9 percent over the rate of income growth for 2013 to 2020 ($1.3605944647 \div 1.3094029651$) that was used in the 2021 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 insurance, workers' compensation, etc.).²¹⁷

Using the 2022 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2021 is $1.3760126457 \div 1.3605944647$, or 1.0113319445. This results in the 2022 required contribution percentage under section 5000A of the Code of 8.00×1.0113319445 or 8.09 percent, when rounded to the nearest one-hundredth of one percent, a decrease of 0.18 percentage points from 2021 (8.09066-8.27392).

Finally, beginning with the 2023 benefit year, we proposed to publish the required contribution percentage, along with the premium adjustment percentage and the annual cost-sharing limitation parameters, in guidance separate from the annual notice of benefit and payment parameters, unless HHS were to propose a change to the methodology for calculating the parameters, in which case, we would do so through notice-and-comment rulemaking. For a discussion of that proposal, please see the preamble for Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130).

We received public comments on the proposed updates to the required contribution percentage (§ 155.605(d)(2)) for plan year 2022. Please see our summary of comments on the

– 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>.

²¹⁷ 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.

premium adjustment percentage (§ 156.130(e)) for a summary of comments on the required contribution percentage.

10. Excluding the Special Enrollment Period Trigger in § 155.420(d)(1)(v) from Applying to SHOP Plans (§ 155.726)

Special enrollment periods due to cessation of employer contributions to COBRA continuation coverage are generally not available in the group insurance market. Therefore, to maintain consistency between SHOP and the rest of the group insurance market, we proposed to amend § 155.726(c)(2)(i) to exclude the special enrollment period trigger in proposed paragraph § 155.420(d)(1)(v) from applying to SHOP plans. However, because proposed paragraph (d)(1)(v) is instead being finalized as paragraph (d)(15), which is not included in § 155.726(c)(2)(i), SHOP plans would no longer be subject to the requirement to offer this special enrollment period. Therefore, there is no need to finalize this provision.

We sought comment on this proposal.

We did not receive public comments on this provision, but are not finalizing this policy as changes to the final regulation at § 155.420 make this unnecessary.

E. Part 156 – Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges

1. User Fee Rates for the 2022 Benefit Year (§ 156.50)

The user fee rates for the 2022 benefit year for issuers on the FFE and SBE-FPs were initially finalized in the final rule published on January 19, 2021 (86 FR 6138 at 6152).

However, as a result of a change in administration priorities, enrollment increases due to legislation and emergency action, and technical improvements we expect increases in the costs of activities related to consumer outreach and Navigators for 2022. Therefore, upon review, we now estimate that the user fees rates established in the January 19, 2021 final rule (86 FR 6138 at 6152) will need to be slightly increased to sustain essential Exchange-related activities and ensure robust outreach to support long-term operational health. HHS intends to propose to

increase FFE and SBE-FP user fee rates for the 2022 benefit year through future notice-and-comment rulemaking. HHS intends to propose a 2022 benefit year user fee rate for all participating FFE issuers at 2.75 percent of total monthly premiums, and a 2022 benefit year user fee rate for all participating SBE-FP issuers at 2.25 percent of total monthly premiums. These user fee rates continue to be lower than the 2021 user fee rates of 3.0 percent of total monthly premiums for all participating FFE issuers and 2.5 percent of total monthly premiums for all participating SBE-FP issuers, but higher than the recently finalized rates of 2.25 percent of total monthly premiums for FFE issuers and 1.75 percent of total monthly premiums for SBE-FP issuers.

a. State User Fee Collection Administration (§ 156.50(c)(2))

We proposed to eliminate the state user fee collection flexibility that HHS had previously offered to states in the 2017 Payment Notice. We proposed that HHS would not collect an additional user fee, if a state so requests, from issuers at a rate specified by the state to cover costs incurred by the state for the functions the state retains. HHS previously provided this flexibility to states to help reduce the administrative burden on states of collecting additional user fees. However, our subsequent internal analysis demonstrated that the process of collecting the state portion of the user fee and remitting it to the state, would increase the operational burden and cost incurred by HHS and no states currently rely on this mechanism. Therefore, we are amending § 156.50(c)(2) to remove this alternate user fee collection mechanism. We noted that this proposal does not change the ability of an SBE-FP to request that HHS collect from the SBE-FP state regulatory entity the total amount that would result from the percent of monthly premiums charged for enrollment through the Federal platform, instead of HHS collecting the fee directly from SBE-FP issuers.

We did not receive public comments on this provision, and therefore, we are finalizing it as proposed.

b. Eligibility for User Fee Adjustments for Issuers Participating through SBE-FPs

(§ 156.50(d))

We proposed to amend § 156.50(d) to clarify that issuers participating through SBE-FPs are eligible to receive adjustments to their federal user fee amounts that reflect the value of contraceptive claims they have reimbursed to third-party administrators (TPAs) that have provided contraceptive coverage on behalf of an eligible employer. In the final rules “Coverage of Certain Preventative Services Under the Affordable Care Act,”²¹⁸ these relationships were established as a method of both providing contraceptives for women and accommodating the religious beliefs of employers. In the 2017 Payment Notice,²¹⁹ we allowed State Exchanges to enter into agreements to rely on the Federal platform for certain Exchange functions to enhance efficiency and coordination between the state and federal programs, and to leverage the systems established by the FFEs to perform certain Exchange functions. Although we recognized that issuers participating in these types of Exchanges were subject to a federal user fee, § 156.50(d) was not amended to reflect the SBE-FP Exchange model. As such, we proposed to amend § 156.50(d) to explicitly include the issuers offering QHPs through SBE-FPs. We also proposed to make conforming changes throughout the regulation text at § 156.50(d) to reflect the user fees applicable to FFEs and SBEs that adopt the DE option, as further discussed elsewhere in this rulemaking.

We sought comment on these proposals.

We received public comments on the proposed updates to eligibility for user fee adjustments for issuers participating through SBE-FPs (§ 156.50(d)). The following is a summary of the comments we received and our responses.

Comment: All commenters supported the proposal for SBE-FP issuers to be eligible to receive adjustments to their user fee amounts for contraceptive claims reimbursed to third-party

²¹⁸ 78 FR 39870 (July 2, 2013); 80 FR 41318 (July 14, 2015).

²¹⁹ 81 FR 12203 at 12293 (March 8, 2016).

administrators. Specifically, a commenter noted their approval of the proposed change because it ensures that issuers in SBE-FP states are not treated less advantageously than issuers in FFE states.

Response: We appreciate the supportive comments on this proposal and are finalizing the policy to amend § 156.50(d) to explicitly include the issuers offering QHPs through SBE-FPs as proposed.

c. Request for Comments on Alternatives to Exchange User Fees (§ 156.50)

In the proposed 2022 Payment Notice, we solicited comment on the appropriateness of an alternative revenue source to Exchange user fees to ensure Exchanges can cover the costs of the Exchange in an effective, appropriate, and fair manner. We appreciate the comments received on this issue, but are not taking any action at this time in relation to Exchange revenue sources. Should we propose future administrative action on this topic, we will review and consider responsive comments at that time.

2. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or after January 1, 2020 (§ 156.111)

a. Annual Reporting of State-Required Benefits

We proposed July 1, 2022 as the deadline for states to submit to HHS their annual reports on state-required benefits pursuant to § 156.111(d) and (f). We are finalizing this deadline as proposed for 2022.

We also intend to exercise enforcement discretion with regard to the first annual reporting submission deadline of July 1, 2021 under current regulation. Pursuant to this enforcement posture, we will not take enforcement action against states that do not submit an annual report in 2021. Rather, we will begin enforcing the annual reporting requirement on July 1, 2022, when states must notify HHS in the manner specified by HHS, of any benefits in addition to EHB and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs in the individual

or small group market are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline).

In the 2021 Payment Notice, we amended § 156.111(d) and added paragraph (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual or small group market that are considered to be “in addition to EHB” in accordance with § 155.170(a)(3) and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination. Under this requirement, a state’s submission must describe all benefits requirements under state mandates applicable to QHPs in the individual or small group market that were imposed on or before December 31, 2011, and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as all benefits requirements under state mandates that were imposed any time after December 31, 2011, applicable to the individual or small group market. The state’s report is also required to describe whether any of the state benefit requirements in the report were amended or repealed after December 31, 2011. Information in the state’s report is required to be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

We also finalized § 156.111(d)(2) to specify that if the state does not notify HHS of its required benefits considered to be in addition to EHB by the annual reporting submission deadline, or does not do so in the form and manner specified by HHS, HHS will identify which benefits are in addition to EHB for the state for the applicable plan year. HHS’s identification of which benefits are in addition to EHB will become part of the definition of EHB for the applicable state for the applicable plan year. In the 2021 Payment Notice, we finalized that we would begin implementation of the annual reporting policy in 2021. Specifically, we finalized that states would be required to notify HHS by July 1, 2021, of any benefits in addition to EHB and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs in the individual or small-group

market are required to cover in plan year 2021 or after plan year 2021 by state action taken by May 2, 2021 (60 days prior to the annual submission deadline).

We are finalizing as proposed a July 1, 2022 deadline for states to submit to HHS a complete reporting package for the second year of annual reporting. As finalized, states are required to notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB and any benefits the state has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline). However, as noted earlier in this section, we also intend to exercise enforcement discretion with regard to the first annual reporting submission deadline of July 1, 2021. Pursuant to this enforcement posture, we will not be actively collecting or requiring submission of annual reports in 2021.

Comment: Many commenters objected to the proposed reporting deadline and asked for a delay in implementation of this policy. Many commenters were against implementation of the annual reporting requirement during the COVID-19 PHE. Commenters explained that imposing this new reporting requirement during a time when states are already required to expend substantial resources to respond to the COVID-19 PHE would add unnecessary burden on states and require states to divert already limited resources away from addressing the COVID-19 PHE. Commenters requested that HHS eliminate the burdensome reporting requirement or, at a minimum, delay reporting until 2023 assuming the end of the COVID-19 PHE in 2021 and economic recovery in 2022.

Other commenters also urged HHS to delay the reporting requirement, arguing that HHS should not implement the annual reporting requirement until HHS releases additional guidance clarifying its defrayal policies as HHS promised it would in the 2021 Payment Notice. These commenters requested that any implementation of the annual reporting policy only occur after states have an opportunity to review the annual reporting process and associated templates in

more depth that HHS will be requiring states to use for annually reporting state mandates to HHS. These commenters noted that states have not yet seen or had an opportunity to review or comment on the proposed annual reporting templates, reiterating the request for HHS to specify with more clarity the reporting and determination mechanisms required of states. Commenters urged HHS to immediately make available the proposed templates that states are expected to use when submitting annual reports.

Commenters also expressed concern about the lack of transparency around the annual reporting and review process, requesting that HHS delay the reporting requirement until HHS provides further clarification. These commenters specifically requested that HHS clarify whether HHS will accept a state's determination as to whether a state mandate is in addition to EHB, who will be the final arbiter of such determinations, and whether there will be any avenue for states to appeal HHS's decisions in situations where there is disagreement between HHS and a state surrounding the scope of a benefit mandate or its status as being in an addition to EHB.

Response: Section 1311(d)(3)(B) of the ACA permits a state to require QHPs offered in the state to cover benefits in addition to the EHB, but requires the 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. Further, section 36B(b)(3)(D) of the Code specifies that the portion of the premium allocable to state-required benefits in addition to EHB shall not be taken into account in determining premium tax credits. We continue to believe that requiring states to annually notify HHS of state-required benefits in the manner specified at § 156.111(d) and (f) will promote compliance with section 1311(d)(3)(B) of the ACA and its implementing regulations at § 155.170. We also believe it will enhance program integrity and potentially reduce improper federal expenditures by supporting HHS efforts to ensure that APTC is paid in accordance with federal law. We also believe the annual reporting policy will increase transparency for issuers, enrollees, and other stakeholders as to which state-required benefits are in addition to EHB. We are proceeding with implementation of the annual reporting policy and

finalizing the second annual reporting deadline of July 1, 2022 as proposed. As finalized, states are required to notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB and any benefits the State has identified as not in addition to EHB and not subject to defrayal, describing the basis for the state's determination, that QHPs are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline).

Although we continue to support implementation of the annual reporting policy, we also acknowledge the validity of commenters' concerns regarding the timing and implementation of annual reporting of state-required benefits as planned in 2021. Therefore, although we are finalizing the second annual reporting deadline of July 1, 2022 as proposed, we also intend to exercise enforcement discretion in relation to the upcoming first annual reporting submission deadline of July 1, 2021. Specifically, HHS will not take enforcement action against states that do not submit an annual report on state-required benefits by the July 1, 2021 submission deadline; and HHS will not identify state-required benefits in addition to EHB for states that do not submit a report to HHS by the July 1, 2021 submission deadline. Accordingly, because HHS is not enforcing the collection of state-required benefits reports in 2021, HHS will not publish on the CMS website in 2021 any annual reports on state-required benefits. We note that the obligation for a state to defray the cost of QHP coverage of state-required benefits in addition to EHB is an independent statutory requirement from the annual reporting policy finalized at § 156.111(d) and (f). Therefore, although this enforcement posture effectively relieves states of state-required benefit reporting requirements until July 1, 2022, it does not pend or otherwise impact the defrayal requirements under section 1311(d)(3)(B) of the ACA, as implemented at § 155.170. Under this enforcement posture, states remain responsible for making payments to defray the cost of additional required benefits and issuers are still responsible for quantifying the cost of these benefits and reporting the cost to the state.

Under this enforcement posture, HHS will begin enforcing the annual reporting requirement on states in 2022. States are required to notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB that QHPs are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline). As part of this reporting, states must also identify which state-required benefits are not in addition to EHB and do not require defrayal in accordance with § 155.170, and provide the basis for the state's determination, by the July 1, 2022 reporting submission deadline. States are permitted to submit their annual report at any time during the May 2 – July 1, 2022, submission window.

In the 2021 Payment Notice, we indicated that we would continue engaging in technical assistance with states to help ensure state understanding of when a state-benefit requirement is in addition to EHB and requires defrayal. We continue to work on additional technical assistance that we believe will further assist states with their defrayal analyses and believe such technical assistance will bolster state compliance with defrayal requirements, as well as result in a smoother annual reporting process for states and review process for HHS. However, we also believe these additional technical assistance documents will best serve state needs if made available to states far enough in advance of the first annual reporting deadline. It is important that states have an opportunity to ask HHS any clarifying questions after reviewing these technical assistance documents and make any necessary adjustments to state policy. We believe that exercising enforcement discretion for the first year of annual reporting in the manner we described will ensure that states have these opportunities before the July 1, 2022 submission deadline. We also believe our enforcement posture will promote a smoother annual reporting process overall in 2022 and beyond as states will be able to utilize the additional technical assistance documents as a tool to identify which state mandates are in addition to EHB in a manner that reflects federal policy.

We also believe the additional technical assistance efforts will help address commenter concerns around potential disagreements between HHS and states as to which state-required benefits are in addition to EHB and require defrayal. The purpose of this additional technical assistance and outreach is to clarify the defrayal policy more generally and to provide states with a more precise understanding of how HHS analyzes and expects states to analyze whether a state-required benefit is in addition to EHB pursuant to § 155.170. We encourage states to review state-required benefits in the context of this additional technical assistance and take the appropriate steps to update policy decisions regarding which state-required benefits are in addition to EHB and require defrayal ahead of the July 1, 2022 annual reporting deadline.

We also acknowledge that states continue to express concern regarding how HHS plans to enforce § 155.170 after reviewing state reports or identifying mandates in a non-reporting state that are in addition to EHB for which the non-reporting state is not defraying. We stated in the 2021 Payment Notice that we would not be adopting any policy with regard to whether enforcement of the defrayal requirement will be retrospective or prospective in relation to the submission of § 156.111 reports. However, we are concerned that declining to adopt an enforcement policy has caused unnecessary confusion and concern for states. We are therefore clarifying that HHS does not intend to retroactively enforce the defrayal requirement against states for plan years prior to 2022 in relation to the submission of § 156.111 reports. With regards to resolving any disagreements that may arise between a state and HHS as to whether a mandated benefit is in addition to EHB, we intend to work closely with the state to address the disagreement without engaging in a formal appeals process. We also intend to provide non-reporting states with an opportunity to review our identifications of state-required benefits that are in addition to EHB prior to releasing the annual reports on the CMS website an effort to mitigate the potential for disagreement between the state and HHS.

As stated in the 2021 Payment Notice, HHS will provide the templates that states are required to use for annually reporting the information required pursuant to § 156.111(f)(1)

through (6). We continue to believe that the descriptions of the required data elements at § 156.111(f)(1) through (6) provide sufficient detail to states regarding the types of information states will be required to include in the annual reports. States and other stakeholders reviewing those requirements should be able to review § 156.111(f)(1) through (6) to better understand the scope of the information states are required to include in their annual reports without reviewing the actual reporting templates. However, we also believe it is important to provide states with ample time to review the precise format, instructions, and content of the annual reporting templates for state-required benefits ahead of submission. As stated in the 2021 Payment Notice, the precise templates that HHS will require states to use are available for review as part of the information collection amended under OMB control number: 0938–1174 (Essential Health Benefits Benchmark Plans (CMS–10448)). Although OMB approved that information collection on February 25, 2021, this approval took longer than anticipated and we agree with commenters that this delay resulted in increasingly limited time for states to review the templates ahead of the July 1, 2021 deadline for the first year of annual reporting of state-required benefits. By exercising enforcement discretion in the manner described, we would provide states that are concerned about having ample time to review the templates ahead of submitting an annual report the option to choose to delay submitting their first annual report until July 1, 2022 without HHS identifying which state-required benefits are in addition to EHB for the applicable plan year in the state.

We also understand that states have an immediate need to devote limited resources to responding to the COVID–19 PHE and that commenters feel that preparing an annual report on state-required benefits in 2021 is competing with that urgent priority. We continue to believe that the information we are requiring that states report to HHS as part of this annual reporting requirement should already be readily accessible to states, as every state should already be defraying the costs of state-required benefits in addition to EHB. Thus, states should already have ready access to the information the annual reports require and the reporting itself should

therefore be complementary to the process the state already has in place for tracking and analyzing state-required benefits. Moreover, states need not report to HHS if they choose not to. Specifically, § 156.111(d)(2) provides that, HHS will identify the state-required benefits it believes are in addition to EHB for the applicable plan year for any state that does not submit an annual report by the annual submission deadline, or does not do so in the form and manner specified by HHS. However, when coupled with the delays in finalizing the reporting templates and issuing additional technical assistance, we believe the added burden of the COVID-19 PHE on states is yet an additional factor that supports exercising enforcement discretion. We believe our enforcement posture for 2021 will allow states that have concerns about the upcoming July 1, 2021 deadline in the context of the COVID-19 PHE sufficient time to prepare their annual reports on state-required benefits before the July 1, 2022 submission deadline.

Comment: Many commenters continue to oppose or be concerned about the annual reporting policy overall and asked HHS for clarity on why HHS has placed a burdensome reporting requirement on states. Commenters stated that HHS has not defined the scope of the problem the reporting seeks to address and asked HHS to provide additional transparency regarding the value that HHS seeks to add in requiring this additional reporting, especially given that some states already conduct defrayal analyses of their own and posts these publicly. Commenters again expressed that the annual reporting requirement is unnecessary, as existing regulation has already established robust requirements for insurers to, in coordination with states and marketplaces, perform actuarially sound analyses of costs associated with state-mandated benefits for use when calculating federal tax credits. Commenters also noted the importance of setting a deadline that allows issuers time to make changes to rate filings. For example, one commenter supported the overall annual reporting policy but requested that HHS adjust the timing and deadlines for the annual reporting to ensure that issuers are aware of any state-mandated benefits that states must defray in advance of rate-setting timelines. This commenter specifically noted that requiring states to file reports by July 1 of the same benefit year does not

provide plans with the time necessary to work such benefits and defrayals into premium calculations for that year.

Response: We disagree with commenters that we have not yet provided adequate justification for why HHS is implementing the annual reporting requirement. When finalizing the annual reporting requirement in the 2021 Payment Notice, we explained the reasoning for the new policy in detail. We also explained that, although we acknowledge that some states may already be appropriately identifying which state-required benefits are in addition to EHB and require defrayal, we believe that many other states may not be doing so. In such states, QHP issuers may be covering benefits as EHB that actually require state defrayal under federal requirements, but for which the state is not actively defraying costs, resulting in improper expenditures of APTC paid by the federal government. Furthermore, requiring states to provide information regarding their state benefit requirements to HHS properly aligns with federal requirements for defraying the cost of state-required benefits; improves transparency with regard to the types of benefit requirements states are enacting; and that it provides the necessary information to HHS for increased oversight over whether states are appropriately identifying which state-required benefits require defrayal and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs. For a more detailed discussion of why the annual reporting policy is justified, please refer to the 2021 Payment Notice.

With regards to the timing of the annual reporting submission deadline, we acknowledge that a July 1 deadline of any given reporting year may not perfectly align with other state and issuer deadlines, such as issuer rate-setting deadlines. However, we remind commenters that states must defray benefits in addition to EHB in accordance with § 155.170 independent of any reporting requirement or reporting timeline and regardless of whether the state benefit requirement is included in that plan year's annual reporting submission. We therefore also conclude that states newly identifying state-required benefits as being in addition to EHB after

rate-setting has concluded is likely not a new issue. In the event that a state newly identifies a state-required benefit as being in addition to EHB and this determination affects issuer rates for the plan year during which the reporting is taking place or for a future plan year, we will work with the state on how to address that situation on a state-by-state basis. We believe that our additional technical assistance and outreach to states will assist in preventing such situations from arising by ensuring that states can analyze pending legislation and state-required benefits in a manner consistent with federal defrayal policy and in advance of rate filing deadlines. However, states that have still concerns about such a situation arising are encouraged to ask HHS in advance of annual reporting submission deadlines for input on whether a state-required benefit is in addition to EHB.

b. States' EHB-Benchmark Plan Options

The 2019 Payment Notice stated that we would propose EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters. In the proposed 2022 Payment Notice, we proposed May 6, 2022, as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year and as the deadline for states to notify HHS that they wish to permit between-category substitution for the 2023 plan year. A typographical error appeared in the proposed rule related to these deadlines. Both proposed deadlines should have read May 6, 2022, for the 2024 plan year, not for the 2023 plan year. The correct meaning of the proposed rule as applying to the 2024 plan year should have been clear from the context of the rulemaking, and the prior rulemaking in the 2021 Payment Notice establishing deadlines for this purpose.

We are finalizing these deadlines with minor revisions to correct the typographical error such that May 6, 2022, is the deadline for states submitting EHB-benchmark plan selections for the 2024 plan year and May 6, 2022, is the deadline for states to permit between-category substitution for the 2024 plan year.

Comment: Commenters requested clarification regarding the proposed submission deadlines. These commenters noted that issuers need sufficient time to review and respond to changes a state may make to its EHB-benchmark plan, and expressed concern that the proposed deadline would occur when issuers are filing plans for 2023. One commenter noted that the proposed reporting deadline is earlier than in prior years and, out of concern for public notice, urged CMS to require states to provide a significant amount of time for the public to comment on any changes that states are planning to make to their EHB-benchmark plans. Another commenter objected to the proposed reporting deadline because it permits EHB-benchmark plan selections to occur on an annual cycle, arguing that by granting states expansive power to alter their EHB-benchmark plans so dramatically every year, the EHB-benchmark plan selection flexibility threatens any hope of predictability of coverage for consumers from year-to-year and state-to-state. We also received several out of scope comments.

Response: We are finalizing as proposed May 6, 2022 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2024 plan year and as the deadline for states to notify HHS that they wish to permit between-category substitution for the 2024 plan year, with minor revisions to correct the typographical error that referred to plan year 2023 in the proposed rule. Fixing this typographical error aligns the deadlines with those finalized in prior years and addresses the concerns commenters raised regarding providing issuers sufficient time to review changes states make to the EHB-benchmark plan and providing the public advance notice of such changes. As in prior years, states are required to provide reasonable public notice and an opportunity for public comment on the state's selection of an EHB-benchmark plan that includes posting a notice on its opportunity for public comment with associated information on a relevant state website. As finalized, the deadlines also allow issuers sufficient time to develop plans that adhere to their state's new EHB-benchmark plan.

As discussed in more detail in the 2019 Payment Notice, the purpose of this policy is to allow for state flexibility in selecting an EHB-benchmark plan, which is why we allow states to

make such changes on an annual basis. Furthermore, because of the level of effort needed by the state and its issuers to make changes to a state's EHB-benchmark plan, we believe that in only very limited cases will a state choose to make EHB-benchmark plan changes on an annual basis, a scenario that has not yet occurred since finalizing the EHB-benchmark plan selection flexibility. If a state does decide to make changes annually, there may be a specific reason for needing an annual change such as for a medical innovation where such benefits would outweigh any potential for consumer confusion.

We continue to emphasize that the deadlines for EHB-benchmark plan selection and permitting between-category substitution are firm, and that states should optimally have one of their points of contact who has been predesignated to use the EHB Plan Management Community reach out to us using the EHB Plan Management Community well in advance of the deadlines with any questions. Although not a requirement, we recommend states submit applications for EHB-benchmark plan selections at least 30 days prior to the submission deadline to ensure completion of their documents by the proposed deadline. We also remind states that they must complete the required public comment period for EHB-benchmark plan selection and submit a complete application by the finalized deadline.

3. Premium Adjustment Percentage (§ 156.130(e))

We proposed the 2022 benefit year annual premium adjustment percentage using the most recent estimates and projections of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) from the NHEA, which are calculated by CMS' Office of the Actuary. For the 2022 benefit year, the premium adjustment percentage will represent the percentage by which this measure for 2021 exceeds that for 2013. However, in light of the overwhelming comments received, we are readopting as the measure of premium growth for the 2022 benefit year and beyond the NHEA projections of average per enrollee employer-sponsored insurance (ESI) premium, which was the measure used for benefit years 2015 through 2019.

Section 1302(c)(4) of the ACA directs the Secretary to determine an annual premium adjustment percentage, a measure of premium growth that is used to set three other parameters detailed in the ACA: (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 ACA 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.

The 2015 Payment Notice final rule and 2015 Market Standards Rule 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. In those rules, HHS used the NHEA ESI premium measure to estimate premium growth. As noted in the 2022 Payment Notice proposed rule, the 2020 Payment Notice final rule changed this methodology and, for benefit years 2020 and 2021, we instead calculated the average per capita premium as private health insurance premiums minus premiums paid for Medicare supplement (Medigap) insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees. Additionally, as finalized in the 2021 Payment Notice final rule, we finalized that we would calculate the payment parameters that depend on NHEA data based on the NHEA data available at the time of the applicable proposed rule.

As such, we proposed that the premium adjustment percentage for 2022 would be the percentage (if any) by which the most recent NHEA projection available at the time of the applicable proposed rule of per enrollee premiums for private health insurance (excluding

Medigap and property and casualty insurance) for 2021 (\$7,036) exceeds the most recent NHEA estimate available at the time of the applicable proposed rule of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 (\$4,883).²²⁰ Using this formula, the proposed premium adjustment percentage for the 2022 benefit year was 1.4409174688 ($\$7,036/\$4,883$), which represents an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 44.1 percent over the period from 2013 to 2021.

We received numerous public comments on the proposed updates to premium adjustment percentage (§ 156.130(e)). Many comments on the premium adjustment percentage were presented alongside comments on related parameters such as the required contribution percentage, maximum annual limitation on cost sharing, and reduced annual limitation on cost sharing. As such, we address comments on all of these parameters in this section. The following is a summary of the comments we received and our responses.

Comment: As has been typical since the change to the methodology was adopted in the 2020 Payment Notice, the majority of commenters requested that we not implement the annual increase to the premium adjustment percentage, or at least one of the parameters derived from this value (for example, the maximum annual limitation on cost sharing, the reduced maximum annual limitations on cost sharing, the required contribution percentage published by HHS), or that the IRS not increase the applicable percentage used to determine premium tax credits, or required contribution percentage for purposes of determining affordability of employer-sponsored minimum essential coverage for determining eligibility for premium tax credits for the 2022 benefit year, and instead requested that HHS revert to the use of the NHEA ESI premium measure to estimate premium growth. Numerous commenters expressed concern with the rate of increase in the premium adjustment percentage and related payment parameters. These commenters specifically opposed the changes made to the premium adjustment percentage

calculation in the 2020 Payment Notice, which based this parameter and the maximum annual limitation on cost sharing, reduced maximum annual limitations on cost sharing, and required contribution percentage on a premium measure that includes individual market premium changes, instead of maintaining the methodology established in the 2015 Payment Notice²²¹ and 2015 Market Standards Rule.²²² These commenters were concerned that the use of a measure that includes individual market premiums has led to more rapid increases in consumer costs than would have occurred had HHS retained the NHEA ESI-only premium measure utilized to calculate the premium adjustment percentage and related parameters prior to the 2020 benefit year.

Commenters also expressed concerns that more rapid increases in the premium adjustment percentage would lead to higher costs to consumers and lower enrollment. A significant majority of these commenters requested that HHS reverse the policy finalized in the 2020 Payment Notice. A few commenters suggested alternatives, including a cap on increases to the maximum annual limitation on cost sharing of 3 percent year-to-year, or a hybrid approach between the pre-2020 and current methodologies. Under the suggested hybrid policy, ESI premiums would be used to calculate the growth in premiums between 2013 and 2019, while all private health insurance premiums minus Medigap and the medical portion of property and casualty insurance would be used to calculate the growth in premiums between 2019 and the current benefit year. These two growth estimates would be multiplied to arrive at the premium adjustment percentage.

Some of these commenters suggested that consumer burden connected to the increases in these parameters has been exacerbated by the COVID-19 PHE and its economic implications. These commenters maintained that these parameters should not be raised during the COVID-19 PHE. However, one commenter specified that they support the flexibility provided by the

²²⁰ 79 FR 13743.

²²² 79 FR 30240.

increase in the maximum annual limitation on cost sharing, which is a result of the increase in the premium adjustment percentage.

Response: After considering the overwhelming comments received, we are reverting to using the NHEA ESI premium measure previously used for the 2015 through 2019 benefit years to estimate premium growth for the 2022 benefit year and beyond. We believe using the NHEA ESI premium measure aligns with the statutory language at section 1302(c)(4) of the ACA, as ESI meets the definition of “health insurance coverage” and represents the vast majority of the market, overlapping very significantly with the private health insurance data used for benefit years 2020 and 2021.²²³

With these considerations, we believe this change is consistent with the will and interest of stakeholders and will mitigate the uncertainty regarding premium growth during the COVID-19 PHE. Reverting to the NHEA ESI premium measure also aligns with the policy objectives in the January 28, 2021 Executive Order on Strengthening the Affordable Care Act and Medicaid²²⁴ and the American Rescue Plan Act of 2021,²²⁵ which both emphasize making health coverage accessible and affordable for consumers of all income levels. Moreover, this policy is consistent with reducing premium growth so that consumers are not required to pay high premiums or cost-sharing that is subsequently rebated pursuant to MLR requirements, particularly since we have seen record high MLR rebates in recent years.²²⁶ ESI premiums have grown at a slower rate from 2013 through 2019 as compared to the private insurance premium growth rate, and when used as a measure of premium growth, ESI premium growth will make more individuals eligible for an affordability exemption that will enable them to enroll in catastrophic coverage under § 155.305(h), will decrease the rate of growth of cost sharing parameters such as the annual maximum limitation on cost sharing, and, if the IRS adopts this measure of premium growth for

²²³ The data used to calculate per capita ESI premiums overlaps significantly with the data used to calculate the current measure—according to the CMS Office of the Actuary, approximately 86 percent of enrollees in 2022 will be covered by employer-sponsored insurance.

²²⁴ 86 FR 7793 (February 2, 2021).

²²⁵ American Rescue Plan Act of 2021, Pub. L. 117-2.

²²⁶ See <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2019-Rebates-by-State.pdf>.

purposes of indexing under the premium tax credit provision in section 36B of the Code going forward, also will increase consumer eligibility for premium tax credits.²²⁷

In addition to aligning with the policy priorities expressed in the recent executive order and statute, reverting to NHEA ESI data as a measure of premium was an explicit interest expressed by commenters to the proposed rule. As noted earlier in this section, the overwhelming majority of commenters specifically opposed the changes made to the premium adjustment percentage calculation in the 2020 Payment Notice and asked HHS to revert to the NHEA ESI premium. We agree with these commenters' concerns.

Furthermore, reverting to NHEA ESI premium data is consistent with changing circumstances related to the potential uncertainty of the private health insurance premium measure that includes the individual market. Private health insurance premiums are more likely to be influenced by risk premium pricing, or premium pricing based on changes in benefit design and market composition in the individual market. Particularly during times of economic uncertainty, such as that experienced as a result of the COVID-19 PHE, private health insurance premium growth could reflect issuer uncertainty in market developments and could be reflected in the NHEA private insurance premium measure (excluding Medigap and property and casualty insurance). NHEA ESI premium data provides a more stable premium measure because it will exclude premiums from the individual market, which are likely to be most affected by the significant changes in benefit design, or risk premium pricing. By using the NHEA ESI premium

²²⁷ 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. Following HHS's establishment of the methodology for calculating premium growth for purposes of the premium adjustment percentage using NHEA ESI for benefit years 2015-2019, and NHEA private health insurance (excluding Medigap and property and casualty insurance), the Department of the Treasury and the IRS issued guidance providing that the rate of premium growth for purposes of the section 36B provisions would be based on the same measures HHS selected. Following this rulemaking, 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. The effects of this change would not be seen in 2022, as the American Rescue Plan Act of 2021 amends the Code to temporarily supersede the indexing for 2021 and 2022, but if the same premium measure was adopted in future tax years, this would result in more individuals being eligible for premium tax credits than would be the case if the current premium measure were maintained.

measure for the 2022 benefit year and beyond, we will provide a more appropriate and fair measure of average per capita premiums for health insurance coverage when considering the goal of consumer protection.

As such, using the NHEA Projections 2019-2028 ESI data available at the time of the proposed rule, the premium adjustment percentage for 2022 is the percentage (if any) by which the NHEA Projections 2019-2028 value for per enrollee ESI premiums for 2021 (\$6,964) exceeds the NHEA Projections 2019-2028 value for per enrollee ESI premiums for 2013 (\$5,061). Using this formula, the premium adjustment percentage for the 2022 benefit year is 1.3760126457 ($\$6,964/\$5,061$) which represents an increase in ESI premiums of approximately 37.6 percent over the period from 2013 to 2021. As described in further detail elsewhere in this preamble, this premium adjustment percentage will be used to index the maximum annual limitation on cost sharing and the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code. It will also be used to index the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code.

Comment: A few commenters asked HHS to coordinate with the Internal Revenue Service (IRS) in setting the maximum annual limitation on cost sharing for high deductible health plans (HDHPs) that would allow enrollees to be eligible to contribute to a Health Savings Account (HSA) so the IRS values match those set in the annual HHS notice of benefit and payment parameters. These commenters were concerned that the differences in these values were confusing to consumers and would lead to an inability for issuers to offer HSA-eligible plans in the bronze metal level.

Response: The Department of the Treasury and the IRS have jurisdiction over HSAs and HSA-eligible HDHPs and the applicable maximum out-of-pocket under section 223 of the Code. Annual adjustments to the maximum annual limitation on cost sharing for HSA-eligible HDHPs are determined under section 223(g) of the Code, which by statute provides for a different annual adjustment than the premium adjustment percentage provided under section 1302(c) of the ACA.

As both of these adjustments are defined in statute, it is not within the authority of HHS to align the premium adjustment percentage with the index used by the IRS for HSA-eligible HDHPs.

Comment: One commenter requested that we reverse the policy we finalized in the 2016 Payment Notice,²²⁸ which clarified that the maximum annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only.

Response: We did not propose and are not finalizing any changes to the policy that the maximum annual limitation on cost sharing for self-only coverage applies to all individuals regardless of whether the individual is covered by a self-only plan or is covered by a plan that is other than self-only. As we stated in the 2016 Payment Notice,²²⁹ we believe that this policy is an important consumer protection, as we were aware that some consumers were confused by the applicability of the annual limitation on cost sharing in other than self-only plans. As such, for all benefit years since 2016, an individual's cost sharing for EHB may never exceed the self-only annual limitation on cost sharing.

Based on the comments received, we are finalizing the premium adjustment percentage for the 2022 benefit year as 1.3760126457 (\$6,964/\$5,061) which represents an increase in ESI premiums of approximately 37.6 percent over the period from 2013 to 2021.

a. Maximum Annual Limitation on Cost Sharing for Plan Year 2022

We proposed to increase the maximum annual limitation on cost sharing for the 2022 benefit year based on the proposed value calculated for the premium adjustment percentage for the 2022 benefit year. As finalized in the EHB final rule²³⁰ at § 156.130(a)(2), for the 2022 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 2022. For other than self-only coverage, the limit is twice the dollar

²²⁸ See 80 FR 10749 at 10824-10825

²²⁹ Ibid.

²³⁰ See 78 FR 12847 through 12848.

limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of \$50.

Using the proposed premium adjustment percentage, 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, 2013,²³¹ we proposed that the 2022 benefit year maximum annual limitation on cost sharing would be \$9,100 for self-only coverage and \$18,200 for other than self-only coverage. This would have represented an approximately 6.4 percent ($\$9,100 \div \$8,550$) increase above the 2021 parameters of \$8,550 for self-only coverage and \$17,100 for other than self-only coverage.

We received public comments on the proposed updates to the maximum annual limitation on cost sharing for plan year 2022. Please see our summary of comments on the premium adjustment percentage (§ 156.130(e)) for a summary of comments on the maximum annual limitation on cost sharing.

We are not finalizing the 2022 maximum annual limitation on cost sharing as proposed. Based on the comments received and as explained above, we are finalizing a 2022 maximum annual limitation on cost sharing of \$8,700 for self-only coverage and \$17,400 for other than self-only coverage. Using the premium adjustment percentage of 1.3760126457 for 2022 finalized in this rule, 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, 2013,²³² the 2022 maximum annual limitation on cost sharing is \$8,700 for self-only coverage and \$17,400 for other than self-only coverage. This represents an approximately 1.8 percent ($\$8,700 \div \$8,550$) increase above the 2021 parameters of \$8,550 for self-only coverage and \$17,100 for other than self-only coverage.

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

We proposed for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking, to use the reductions in the maximum annual limitation on cost sharing for

²³¹ See Revenue Procedure 2013-25, 2013-21 IRB 1110. <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

²³² See Revenue Procedure 2013-25, 2013-21 IRB 1110. <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

cost-sharing plan variations determined by the methodology we established beginning with the 2014 benefit year, as further described later in this section of the preamble.

Sections 1402(a) through (c) of the ACA 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 CSRs. Specifically, in part 156 subpart E, we specified that QHP issuers must provide CSRs 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 ACA, section 1402(c)(1)(B)(ii) of the ACA 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) of the ACA (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee).

As we stated earlier in this final rule, the proposed 2022 maximum annual limitation on cost sharing was \$9,100 for self-only coverage and \$18,200 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2022 plan year and our proposed results.

Consistent with our analysis for the 2014 through 2021 benefit years' reduced maximum annual limitation on cost sharing, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the ACA to the proposed estimated 2022 maximum

annual limitation on cost sharing for self-only coverage (\$9,100). The test plan designs are based on data collected for 2021 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 2022, the test silver level QHPs included a PPO with typical cost-sharing structure (\$9,100 annual limitation on cost sharing, \$2,775 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing (\$7,400 annual limitation on cost sharing, \$3,050 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$9,100 annual limitation on cost sharing, \$4,800 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, \$30 primary care office visit, and \$55 specialist office visit). Based on the parameters in the proposed rule, all three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into a draft version of the 2022 benefit year AV Calculator²³³ and observed how the reductions in the maximum annual limitation on cost sharing specified in the ACA affected the AVs of the plans. As with prior years, we found that the reduction in the maximum annual limitation on cost sharing specified in the ACA 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), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively).

However, as with prior years, we continue to find that the reduction in the maximum annual limitation on cost sharing specified in the ACA for enrollees with a household income between 200 and 250 percent of FPL (1/2 reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. Furthermore, as with prior years, for individuals with household incomes of 250 to 400 percent of FPL, without any change in other

²³³ Available at <https://www.cms.gov/cciiio/resources/regulations-and-guidance/index>.

forms of cost sharing, the statutory reductions in the maximum annual limitation on cost sharing would cause an increase in AV that exceeds the maximum 70 percent level in the statute.

The calculation of the reduced maximum annual limitation on cost sharing has remained consistent since the 2014 Payment Notice due to year-over-year consistency of the results of our analysis regarding the effects of the reduced maximum annual limitation on cost sharing on the AV of silver plan variations. Therefore, as a result of the apparent stability of those results, and consistent with prior Payment Notices, we proposed to continue to use the maximum annual limitation on cost sharing reductions of $\frac{2}{3}$ for enrollees with a household income between 100 and 200 percent of FPL, $\frac{1}{5}$ for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond. We would continue to review the effects of these reductions annually, and should we determine that this approach should be changed to better reflect the statutorily specified AVs for silver plan variations, we would propose to change these reductions through notice-and-comment rulemaking.

Specifically, we proposed to continue to use the methodology described above for analyzing the effects of the reduced maximum annual limitations on cost sharing on the AV of silver plan variations to verify that the reductions do not result in unacceptably high AVs before we publish these values in guidance for a given benefit year. Subsequently, if a future analysis using this methodology supports a modification to the reduced maximum annual limitation for any of the household income bands for a future benefit year, we would propose those modifications to the reduced maximum annual limitations through notice-and-comment rulemaking, as appropriate.

We noted that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in the aggregate. This is because QHP issuers are required to meet specified AV levels that require the plan's cost-sharing to be within a limited range.

We sought comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing calculation methodology for the 2022 benefit year and beyond. We also sought comment on the proposed reduced annual limitations on cost sharing for the 2022 benefit year.

We noted that for 2022, as described in § 156.135(d), states are permitted to request HHS's approval for state-specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1, 2020 deadline.

We received no comments on the reductions in the maximum limitations on cost sharing apart from those already discussed in the preamble to the premium adjustment percentage (§ 156.130(e)). In this regard, please see our summary of comments on the premium adjustment percentage (§ 156.130(e)) for a summary of comments pertaining to the reduced maximum annual limitation on cost sharing.

In light of our decision to finalize the 2022 premium adjustment percentage using the NHEA ESI premium measure to estimate premium growth, we are not finalizing the 2022 reduced maximum annual limitation on cost sharing parameters as proposed (in Table 9 of the proposed rule²³⁴).

To confirm consistency with the analysis for the reduced maximum annual limitation on cost sharing, we tested the reductions to the maximum annual limitation for cost sharing which we are finalizing in this rule, and we analyzed the impact on AV of the reductions described in the ACA to the 2022 maximum annual limitation on cost sharing that we are finalizing (\$8,700). For 2022, the test silver level QHPs included a PPO with typical cost-sharing structure (\$8,700 annual limitation on cost sharing, \$2,600 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing (\$7,700 annual limitation on cost sharing, \$2,800 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$8,700 annual limitation on cost sharing, \$4,100 deductible, 20 percent in-network coinsurance rate, and

²³⁴85 FR 78572 at 78635.

the following services with copayments that are not subject to the deductible or coinsurance: \$1200 inpatient stay per day, \$500 emergency department visit, \$30 primary care office visit, and \$60 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans based on the parameters that we are finalizing in this rule.

We then entered these test plans into a draft version of the 2022 benefit year AV Calculator²³⁵ and observed how the reductions in the maximum annual limitation on cost sharing specified in the ACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the ACA 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), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels.

Therefore, we are finalizing as proposed the reductions of 2/3 for enrollees with a household income between 100 and 200 percent of FPL, 1/5 for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond, as well as the methodology we use to ensure that these reductions do not result in unacceptably high AVs. The resulting final 2022 reduced maximum annual limitations on cost sharing are available in Table 10 below.

TABLE 10: Reductions in Maximum Annual Limitation on Cost Sharing for 2022

Eligibility Category	Reduced Maximum Annual Limitation on Cost Sharing for Self-only Coverage for 2022	Reduced Maximum Annual Limitation on Cost Sharing for Other than Self-only Coverage for 2022
Individuals eligible for CSRs under § 155.305(g)(2)(i) (100-150 percent of FPL)	\$2,900	\$5,800
Individuals eligible for CSRs under § 155.305(g)(2)(ii) (151-200 percent of FPL)	\$2,900	\$5,800
Individuals eligible for CSRs under § 155.305(g)(2)(iii) (201-250 percent of FPL)	\$6,950	\$13,900

²³⁵ Available at https://www.cms.gov/cciiio/resources/regulations-and-guidance/index_

c. Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130)

Since the 2014 benefit year, HHS has published the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage parameters through notice-and-comment rulemaking. Beginning with the 2023 benefit year, we proposed to publish these parameters in guidance by January of the year preceding the applicable benefit year, unless HHS is changing the methodology for calculating the parameters, in which case, we would do so through notice-and-comment rulemaking. We additionally proposed to publish in guidance the premium adjustment percentage and related parameters using the most recent NHEA income and premium data that is available at the time these values are published in guidance or, if HHS is changing the methodology for calculating these parameters, at the time these values are proposed in notice-and-comment rulemaking. Publication of these parameters prior to the release of updates to the NHEA data, which typically (but not always) occurs in February or March, is consistent with the 2021 Payment Notice policy to finalize the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage using NHEA data that would be available at the time that the proposed rule would have been published.

In the EHB final rule,²³⁶ HHS established at § 156.130(e) that HHS will publish the annual premium adjustment percentage in the annual HHS notice of benefit and payment parameters. Additionally, in the 2014 Payment Notice final rule,²³⁷ HHS established at § 156.420(a)(1)(i), (2)(i), and (3)(i), that the reduced annual limitations on cost sharing would be published in the applicable benefit year's annual HHS notice of benefit and payment parameters.

²³⁶ 78 FR 12834 through 12833.

²³⁷ 78 FR 15409.

Due to the timing of publication of the annual HHS notice of benefit and payment parameters final rule in past years, stakeholders have suggested that when HHS is not changing the calculation methodology for these parameters, HHS should publish earlier the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage. These stakeholders asserted that an earlier publication would allow issuers to incorporate these parameters for rate setting and the submission of QHP benefit templates earlier than would be possible if the parameters were published in the applicable benefit year's notice of benefit and payment parameters.

In addition, once the methodologies used to calculate the premium adjustment percentage, required contribution percentage, and maximum annual limitation on cost sharing have been established through rulemaking, the calculation of these amounts is a function of entering the applicable figures into the established equations, and therefore, does not require rulemaking to establish in subsequent benefit years. Furthermore, the methodology used to calculate the reduced maximum annual limitation on cost sharing has remained consistent since the 2014 Payment Notice final rule. Therefore, as discussed earlier in this final rule, we are finalizing for the 2022 benefit year and beyond the reduction rates for the reduced maximum annual limitation on cost sharing as well as the methodology for determining whether these reductions raise plan AVs above acceptable levels for the 2022 benefit year and beyond.

With these methodologies in place we proposed to amend §§ 156.130(e) and 156.420(a) to reflect that, beginning with the 2023 benefit year, we would publish the premium adjustment percentage, along with the maximum annual limitation on cost sharing, the reduced maximum annual limitation on cost sharing, and the required contribution percentage, in guidance by January of the year preceding the applicable benefit year (for example, the 2023 premium adjustment percentage would be published in guidance no later than January 2022), unless HHS is amending the methodology to calculate these parameters, in which case HHS would amend the methodology and publish the parameters through notice-and-comment rulemaking.

We believed that publishing the final premium adjustment percentage and associated final parameters in guidance annually instead of through notice-and-comment rulemaking is consistent with our efforts to provide information to stakeholders in a timely manner.

We received public comments on the proposal to publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing (§ 156.130), and required contribution percentage (§ 155.605(d)(2)) in guidance. The following is a summary of the comments we received and our responses.

Comment: We received multiple comments expressing general support for publishing the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage in guidance by January of the year proceeding the applicable benefit year, when we are not proposing any changes to the methodologies used to calculate these values. Commenters largely agreed that this publication timeline would reduce confusion and would provide information to stakeholders in a more timely manner.

However, a few commenters expressed concern that publication in guidance would reduce their opportunities to review and comment on these parameters. Some of these commenters pointed out that their concerns regarding the 2020 Payment Notice change in the premium adjustment percentage calculation²³⁸ have not been addressed and feared that publishing these parameters in guidance would remove opportunity to comment on the current methodology. For this reason, one commenter asked that we publish the parameters in guidance in draft form seeking public comment prior to finalizing the parameters for the applicable benefit year.

Response: We are finalizing our ability to publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing

²³⁸ In the 2020 Payment Notice, HHS changed the methodology for calculating the premium adjustment percentage from using ESI premiums to using all individual health insurance premiums minus Medigap and the medical portion of property and casualty insurance. See 84 FR 17454.

and required contribution percentage in guidance. Therefore, for the 2023 benefit year and beyond, the values calculated based on the methodologies established in rulemaking will generally be published in guidance by January of the year preceding the benefit year to which they apply, unless we are proposing changes to the methodology used to calculate these values or otherwise wish to discuss or obtain significant feedback on the methodology. As a general matter, we do not believe that comments to such guidance will be necessary since the methodology will have been set pursuant to statute and through notice-and-comment rulemaking, and the guidance would merely be announcing the published measures and showing the calculations based on the established methodology and published measures. We reiterate that if we do propose changes to the methodology, we will propose the values of these parameters alongside the changes in methodology through notice-and-comment rulemaking.

As mentioned in previous sections of this final rule, we have addressed comments concerned about the methodology change for calculating the premium adjustment percentage that was finalized in the 2020 Payment Notice, and are reverting back to the methodology used prior to 2020 Payment Notice. Therefore, we are relying on NHEA ESI premium data, not premium data from other private health insurance markets, in our calculation of premium growth and the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage for the 2022 benefit year and beyond.

4. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

In the 2021 Payment Notice, we finalized a requirement that under § 156.270(b)(1), QHP issuers must send termination notices with effective dates and reason for the termination to enrollees for all termination events. We finalized this policy as proposed, noting that all commenters who weighed in on this topic supported our proposal. This policy became effective July 13, 2020. In the 2022 Payment Notice proposed rule, we did not propose, and we are not

finalizing, any changes to paragraph (b)(1) beyond what we finalized in the 2021 Payment Notice for the reasons discussed below.

In finalizing the change to § 156.270(b)(1) in the 2021 Payment Notice, we inadvertently omitted discussion of two comments opposing the proposal. These comments raised concerns about unnecessary additional administrative costs and IT builds, and noted that a termination notice could be confusing in certain scenarios—for example, if the enrollee switches between QHPs offered by the same issuer, a termination notice from their issuer could cause confusion. These commenters proposed instead that Exchanges should be required to clearly convey the eligibility termination reason and effective date in the Exchange’s own eligibility notices, consistent with the data conveyed to issuers on 834 termination transactions.

We are sensitive to commenters’ concerns that issuers need sufficient time to build IT systems to implement this policy. In response, we issued guidance allowing issuers using the Federal platform enforcement discretion until February 1, 2021 to implement the new termination notice requirement.²³⁹

However, the comments in opposition to the proposal do not change our policy goals underlying our decision to finalize the rule as proposed. FFEs do not send termination notices for any termination scenario other than citizenship data-matching issue expirations and terminations associated with Medicare PDM when the enrollee has elected at plan selection to terminate Exchange coverage when found dually enrolled. FFEs also do not send termination notices in enrollee-initiated terminations which must be requested at the Exchange. Similarly, FFEs do not send termination notices when an enrollee switches QHPs within the same issuer. This is all appropriate, because the issuer is the primary communicator to the enrollee about their coverage. We still believe that termination notices would be helpful in these scenarios, even in plan selection changes, because an enrollee switching QHPs could have their premium, cost sharing,

²³⁹ “Enforcement Safe Harbor for Qualified Health Plan Termination Notices During the 2019 Benefit Year,” August 26, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Termination-Notices-Enforcement-Discretion.pdf>.

and provider network affected. As one of the comments in support of the new termination notice requirement in the 2021 Payment Notice noted, it is important for the enrollee to have in writing the actual termination date for their records, in case of miscommunication with the issuer about the preferred date or to later dispute an inaccurate Form 1095-A. Another commenter agreed that issuers should send termination notices during voluntary terminations associated with Medicare PDM as it would help the enrollee confidently transition to Medicare.

Complaints about terminations are one of the largest sources of casework. More consistent communication is part of the solution. We believed consumers should be notified of these changes, even if they initiated them, so that enrollees have a record that the issuer completed the request. Issuers are the proper messenger of termination noticing for many reasons. For example, Exchange issuers historically are the senders of termination notices, and some issuers acknowledged in their comments on the 2021 Payment Notice that they already do send termination notices in all scenarios. Furthermore, the issuer has record of the termination date needed for the termination notice before the Exchange in some cases, such as some retroactive termination requests handled through casework, and State Exchange issuer terminations described in § 155.430(d)(iv). One reason we regulated in this area is that we were receiving detailed questions from issuers about which termination scenarios required issuer notices; we believe requiring issuer termination notices for all scenarios in the long run makes the requirement simpler.

Therefore, we did not propose, and are not finalizing, any changes to § 156.270(b)(1) beyond what we finalized in the 2021 Payment Notice.

Comment: One commenter appreciated that we did not propose any changes beyond what we finalized in the 2021 Payment Notice. Another commenter supported our 2021 Payment Notice provision requiring issuers to send termination notices to consumers in all termination scenarios, but suggested that HHS work with consumer advocates to provide simpler, more

easily understandable termination templates that could help with readability for individuals with low literacy.

Response: HHS does not proscribe language that issuers must use in their termination notices. We believe that issuers, as the primary communicators to enrollees about their coverage, are in the best position to decide the appropriate termination notice content and wording for their enrollees, as long as they comply with applicable requirements, including those in §§ 156.270 and 156.250. Under those regulations, because issuers are required to send these termination notices to enrollees, issuers must use plain language in any such notices they send to consumers, so that the information can easily be understood and is useful to consumers with low literacy, low health literacy, or limited English proficiency.

Comment: One commenter said that FFEs, as the systems of record, should be responsible for sending termination notices, particularly because FFEs already send eligibility notices, 1095-A forms, and other documentation.

Response: As we explained in the preamble to the proposed rule, issuers are the proper messenger of termination noticing for many reasons. Exchange issuers historically are the senders of termination notices, and some issuers acknowledged in their comments on the 2021 Payment Notice that they already do send termination notices in all scenarios. Furthermore, the issuer has record of the termination date needed for the termination notice before the Exchange in some cases, such as some retroactive termination requests handled through casework, and State Exchange issuer terminations described in § 155.430(d)(iv).

5. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295)

Section 6005 of the ACA added section 1150A(a)(2) of the Act to require a PBM under a contract with a Medicare Part D plan sponsor or Medicare Advantage plan that offers a Medicare Part D plan, or with a QHP offered through an Exchange established by a state under section

1311 of the ACA²⁴⁰ to provide certain prescription drug information to the Secretary, at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer or their PBM must report.²⁴¹ Section 1150A(c) of the Act requires the information reported to be kept confidential and not to be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.²⁴²

In the 2012 Exchange Final Rule, we codified the requirements contained in section 1150A of the Act with regard to QHPs at § 156.295. In that rule, we interpreted section 1150A of the Act to require QHP issuers to report the information described in section 1150A(b) of the Act and did not specify the responsibilities of PBMs that contract with QHP issuers to report this information. On January 28, 2020²⁴³ and on September 11, 2020,²⁴⁴ we published notices in the **Federal Register** and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act to HHS.²⁴⁵

²⁴⁰ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the ACA. *King v. Burwell*, 576 U.S. 988 (2015).

²⁴¹ This information is: the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract; the aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and, the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

²⁴² The purposes are: as the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the ACA.

²⁴³ 85 FR 4993 through 4994.

²⁴⁴ 85 FR 56227 through 56229.

²⁴⁵ Pharmacy Benefit Manager Transparency. CMS-10725. Available at <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pa-listing/cms-10725>.

a. QHP Issuer Responsibilities

In the proposed rule, we proposed to add new part 184 to address the responsibilities of PBMs under the ACA and to add § 184.50 to codify in regulation the statutory requirement that PBMs that are under contract with an issuer of one or more QHPs report the data required by section 1150A of the Act. Accordingly, we proposed to revise § 156.295(a) to state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs, the QHP issuer will report the data required by section 1150A of the Act to HHS. We proposed corresponding revisions throughout § 156.295 to remove the applicability of the reporting requirement for PBMs under this section and propose revising the title to “Prescription drug distribution and cost reporting by QHP issuers”.

As explained in the proposed rule and in the preamble for § 184.50 in this final rule, we acknowledge that section 1150A places responsibility on both the QHP issuer and their PBMs to report this prescription drug data. Generally, where a QHP issuer contracts with a PBM, the PBM is more likely to be the source of the data that must be reported. Therefore, to reduce overall burden, rather than requiring the QHP issuer to serve as a conduit between its PBM and HHS, or unnecessarily requiring both the PBM and the QHP issuer to submit duplicated data, we proposed to implement section 1150A to make QHP issuers responsible for reporting this data directly to the Secretary only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Where a QHP contracts with a PBM, the PBM is responsible for reporting data to the Secretary as required by § 184.50.

We stated that although we were unaware of any QHP issuer that does not currently utilize a PBM, we believed that, together, the proposals to revise § 156.295 and to add § 184.50 would ensure the collection of data required by section 1150A of the Act in all circumstances, including when a QHP issuer does not use a PBM to administer its prescription drug benefit. Retaining the requirement for QHP issuers to report data at § 156.295 when they do not contract with a PBM would ensure that the data is consistently collected every plan year.

We also proposed to remove § 156.295(a)(3) to remove the requirement for QHP issuers to report spread pricing amounts when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Spread pricing amounts are only present where a PBM acts as an intermediary between the QHP issuer and a drug manufacturer. If a QHP issuer does not contract with a PBM, no such intermediary exists and it is not possible for QHP issuers to report this data.

We sought comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to collect this data directly from the PBMs that QHP issuers contract with to administer the drug benefit for their QHPs, as PBMs are best positioned to report the data with the least amount of burden. A few commenters asserted that section 1150A(a)(2) of the Act does not grant HHS the authority to collect this data directly from PBMs.

Response: We agree with commenters that where QHP issuers utilize PBMs to administer their prescription drug benefit, PBMs are best suited to report this data. Section 1150A(a)(2) of the Act grants the Secretary the authority to specify the time, form, and manner of this collection. We exercise this authority to specify the manner of this collection by finalizing this policy as proposed: PBMs will submit this data to HHS when a QHP issuer contracts with the PBM to administer the drug benefit for their QHPs. If a QHP issuer does not contract with a PBM to administer the drug benefit for their QHPs, the QHP issuer will submit the data to HHS. However, given our understanding that all QHP issuers currently use a PBM, with the limited exception of QHP issuers with integrated delivery systems as discussed below, we believe that it is reasonable to expect that PBMs are best suited to report this data given their contractual role in the primary administration of prescription drug benefits.

Comment: Citing the burden to make contractual modification and operational upgrades, many commenters requested that we delay implementation of the collection until 2022 or later.

Response: We are aware of the timing concerns expressed by commenters in response to the policies finalized here and at part 184 below, as well as those expressed in response to the collection of information requirement notices displayed in 2020. However, this collection is statutorily required, and, as noted in the collection of information requirement notices, we have previously delayed its implementation in order to accommodate concerns regarding burden. We are sensitive to commenters' concerns about burden and timing, and, this data collection is not imposed lightly; we understand that the implementation of a new data collection during a pandemic may impose additional challenges on the industry. However, its disclosure has never been more vital, as all aspects of the prescription drug delivery chain continue to contribute to rising prescription drug costs in this country. Additionally, we believe that this data is essential for the implementation of policies that seek to improve the coverage landscape of prescription drugs. We therefore intend to begin collection as soon as reasonably possible. However, to minimize burden during a pandemic, and to allow for additional time to provide technical assistance to reporting entities for a new collection, we do not intend to require submission sooner than December 31, 2021.

Comment: Multiple commenters asserted that section 1150A(a)(2) of the Act does not grant HHS the authority to collect some of this data at the National Drug Code (NDC) level of detail. Commenters also expressed concern that HHS did not describe the level of detail for this collection in regulation.

Response: Section 1150A(a)(2) of the Act grants the Secretary the authority to specify the time, form, and manner of this collection. We have specified the form and manner of this collection as part of the collection of information requirement notices displayed in 2020. In collecting some of this data at the NDC level of detail, we are interpreting section 1150A in a

manner consistent with previous rulemaking by CMS.²⁴⁶ Additionally, we sought comment on the form and manner of the collection twice in the collection of information requirement notices displayed in 2020, including the level of detail of the collection.

Comment: Some commenters expressed concern that a federal requirement to report prescription drug data for QHPs may conflict or overlap with state requirements to collect similar data. One commenter voiced concern that this collection is unduly similar to the Transparency in Coverage final rule,²⁴⁷ a rule for which the commenter seeks regulatory clarifications.

Response: While we agree with commenters that we should endeavor to minimize burden and avoid conflict or duplication of efforts with state reporting requirements, we have conducted research and held discussions with states to understand existing state reporting requirements. In addition, no state submitted comments to the collection of information requirement notices displayed in 2020 or to this proposal indicating any concern about conflict or overlap with this reporting requirement. As a result, we believe that there is no significant conflict or duplication between this collection and any state reporting requirement.

We also note that, after the proposed rule displayed, Congress passed the Consolidated Appropriations Act, 2021,²⁴⁸ which includes certain reporting requirements on pharmacy benefits and drug costs.²⁴⁹ We are aware that some of the data envisioned for reporting under the Consolidated Appropriations Act may, to an extent, be similar to some of the data sought by collection under § 1150A of the Act. While we are finalizing this collection as proposed, we,

²⁴⁶ See “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule” at 77 FR 22094. In that final rule, CMS interpreted section 1150A of the Act to impose no additional reporting requirements for entities subject to Direct and Indirect Remuneration (DIR) reporting, except for PBM spread amount aggregated to the plan benefit package level. The existing DIR reporting required data reporting at the NDC. As such, CMS has previously interpreted that section 1150A authorizes collection at an NDC level of reporting. For consistency with previous rulemaking by CMS and to reduce the burden of creating different CMS collection requirements, we will collect some of this data at the NDC level. We recognize that DIR reporting requirements under Part D are partly based on statutory authority that is not applicable to this collection, and we do not claim to rely on any authority other than section 1150A of the Act as the basis for this collection. We do, however, rely on that final rule insofar as CMS strives to interpret the same statute consistently.

²⁴⁷ 85 FR 72158.

²⁴⁸ Pub. L. 116-260, enacted on December 27, 2020.

²⁴⁹ See section 2799A-10.

along with the Departments of Treasury and Labor, intend to issue future guidance that will explain the interaction between this collection and the future collection envisioned by the Consolidated Appropriations Act, if necessary.

Comment: One commenter requested clarification whether the collection applies to QHP issuers with integrated delivery systems; that is, QHP issuers that do not use a network of outside providers and do not use outside PBMs to manage their prescription drug benefits. This commenter asserted that there is limited rationale to collect data from such plans, as § 1150A is intended to increase transparency on relationships and transactions across the prescription drug supply chain, particularly between health plans, PBMs, and pharmacies.

Response: We recognize that not all data elements that must be reported under this requirement would apply equally to integrated delivery systems. Nonetheless, we believe that it is important for these QHP issuers with integrated delivery systems to report the data elements that are applicable, since these issuers are also part of the drug supply chain and their different model provides an important point of comparison. In this instance, the QHP issuer would be responsible for reporting this data, as they do not utilize a PBM to administer their prescription drug benefit. We plan to provide technical assistance to all reporting entities to minimize the burden of this collection.

Comment: One commenter requested clarification regarding the collection's applicability to off-Exchange plans.

Response: This collection applies to QHPs only. We interpret the statute as requiring reporting for QHPs, regardless of whether the QHPs are sold on-Exchange or off-Exchange. The collection does not apply to any other plans.

Comment: A few commenters addressed the confidentiality provision of section 1150A and their codification in regulation. A few commenters requested that the data be released to the public in Public Use Files (PUFs). A few commenters noted that we should share this data with states upon their request to bolster their transparency efforts. One commenter asserted that the

confidentiality restrictions required by statute may be too limiting to have an appreciable impact on reducing health care costs for patients, employers and other purchasers.

Response: Section 1150A of the Code, codified previously at § 156.295 and also finalized below at § 184.50 states that information disclosed by a plan or PBM under this collection is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for certain purposes, including to states to carry out section 1311 of the ACA.²⁵⁰

Comment: We received a number of comments that were out-of-scope of the two specific proposals in the proposed rule, including suggestions for improving the definition of “bona fide service fees” used in the appendices of the previously posted ICRs, suggestions on how we might automate the reporting mechanisms, and comments regarding the transparency in coverage requirement under PHS Act section 1311(e)(3).

Response: We appreciate these suggestions and will consider them for future action for this collection and its associated regulations. However, as they are out-of-scope with regards to these specific proposals, we decline to comment further on them at this time.

As a result of the comments, we are finalizing this policy as proposed.

b. Reporting of Data by Pharmacy Type

Section 1150A(b)(1) of the Act requires the Secretary to collect certain QHP prescription drug data²⁵¹ by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). This requirement was previously codified at § 156.295(a)(1). In the Medicare Program; Changes to the Medicare Advantage and

²⁵⁰ The other purposes described in statute are: as the Secretary determines to be necessary to carry out section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; and, to permit the Director of the Congressional Budget Office to review the information provided.

²⁵¹ Section 1150A(b)(1) requires the reporting of the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed.

the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule, we recognized that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files.²⁵² We understand that these types continue not to be standard classifications currently captured in industry databases or files, as indicated by comments submitted in response to the January 28, 2020 notice in the **Federal Register** soliciting public comment on the collection of information requirements of this collection.²⁵³ To reduce the burden of this collection, we proposed to revise § 156.295(a)(1) to remove the requirement to report the data described at section 1150A(b)(1) of the Act by pharmacy type. We intended to collect this information at a time when this requirement would impose reasonable burden. We sought comment on ways that we may collect the data by pharmacy type without creating unreasonable burden and any existing definitions that may exist that could be leveraged for this purpose. We also sought comment on the time and costs required for PBMs to begin reporting by pharmacy type, if definitions were finalized.

We received public comments on the proposed updates to reporting of data by pharmacy type. The following is a summary of the comments we received and our responses.

Comment: Nearly all commenters supported the proposal to remove the requirement to report the data described at section 1150A(b)(1) of the Act by pharmacy type, agreeing that it is not a data point that is collected on a widespread basis by the industry and that the implementation would cause unreasonable burden. One commenter disagreed, explaining that that industry is currently capable of reporting this data.

Response: We agree with the majority of commenters that pharmacy type data is currently not readily collected by industry. While we will continue to consider ways to

²⁵² See 77 FR 22072 at 22093.

²⁵³ See 85 FR 4993 through 4994.

implement its collection, we agree that removal of this requirement from the regulation is warranted at this time.

Following review of the comments, we are finalizing this policy as proposed.

6. Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, and User Fee Programs (§ 156.480)

a. Application of Requirements to Issuers in State Exchanges and SBE-FPs

In the second Program Integrity Rule, we finalized general provisions related to the oversight of QHP issuers in relation to APTC and CSRs.²⁵⁴ We explained that since APTC and CSR payments are federal funds which pass from HHS directly to QHP issuers, it is necessary for HHS to oversee QHP issuer compliance in these areas, regardless of whether the QHP is offered through a State Exchange or an FFE. As such, to effectively oversee the payment of APTC and CSRs by QHP issuers, HHS established standards in part 156, subpart E for QHP issuers participating in FFEs and State Exchanges. We also noted that in states with State Exchanges, the state would have primary enforcement authority over QHP issuers participating in the state's individual market exchange that were not in compliance with the standards set forth in part 156, subpart E.²⁵⁵ However, if the State Exchange does not enforce such standards, HHS would enforce compliance with these requirements, including the imposition of CMPs on QHP issuers participating in State Exchanges using the same standards and processes for QHP issuers participating in FFEs set forth in part 156, subpart I.²⁵⁶ In the second Program Integrity Rule, we also finalized general provisions that require issuers offering QHPs in an FFE maintain all documents and records and other evidence of accounting procedures and practices, which are critical for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs.²⁵⁷ As finalized in 45 CFR 156.705(a)(1), this includes the authority for

²⁵⁴ See 78 FR 65077 and 65078.

²⁵⁵ See the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR 65077 and 65078.

²⁵⁶ Ibid.

²⁵⁷ See 78 FR 65078 and 65079.

HHS to include periodic auditing of the QHP issuer's financial records related to the participation in an FFE. To date, we have leveraged this authority to conduct user fee audits of QHP issuers participating in an FFE.

In the proposed rule, we proposed amendments to consolidate HHS audit authority regarding APTC, CSR, and user fee audits by expanding the audit authority under § 156.480(c) to also capture user fees audits by HHS, or its designee, of QHP issuers participating in an FFE. Additionally, as part of determining whether APTC and CSR amounts were properly paid to issuers, and whether user fee amounts were properly collected, we explained that HHS regularly identifies discrepancies in issuer records caused by issuer non-compliance with other applicable Exchange operational standards. Examples include failure to correctly effectuate or terminate coverage, or to correctly calculate premiums. In addition, we proposed to apply the same framework to QHP issuers participating in SBE-FP states. As such, QHP issuers in SBE-FP states would be required to comply with HHS audits under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees.

We further proposed that in situations where the state fails to substantially enforce such standards, HHS would enforce compliance, including imposing CMPs using the same standards set forth in part 156, subpart I. Based on our experience conducting audits of APTC, CSRs, and user fees, we also proposed several amendments to § 156.480(c) to ensure we can effectively oversee the payment of these amounts by QHP issuers, regardless of Exchange type (for example, FFE, State Exchange, or SBE-FP).

As detailed below, to further support our program integrity efforts in these areas, we proposed to amend § 156.480(c) to codify additional details regarding HHS audits and to capture authority for HHS to conduct compliance reviews of QHP issuer compliance with the applicable

federal APTC, CSR, and user fee standards,²⁵⁸ including the consequences for the failure to comply with an audit. In addition, we proposed amendments to §§ 156.800 and 156.805 to set forth the framework for HHS enforcement of the applicable federal APTC, CSR, and user fee standards in situations where state authorities fail to substantially enforce those standards with respect to the QHP issuers participating in State Exchanges and SBE-FPs.

We sought comment on these proposals, including with respect to how HHS could coordinate with State Exchanges and SBE-FPs to address non-compliance by QHP issuers with applicable federal APTC, CSRs, and user fee standards. We sought comment on ways to balance enforcement by State Exchanges and SBE-FPs and the protection and oversight of federal funds by HHS. We are finalizing the proposal to apply the same audit requirements to QHP issuers participating in SBE-FP states as for QHP issuers participating in FFE states. As such, QHP issuers in SBE-FP states will be required to comply with HHS audits under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees. We are also finalizing the APTC, CSR, and user fee audit requirements at § 156.480(c) with slight modifications to certain audit timeframes, as well as HHS's authority to impose CMPs on issuers in State Exchanges and SBE-FPs when the State Exchange or SBE-FP fails to substantially enforce the applicable federal APTC, CSR, and user fee standards at §§ 156.800 and 156.805. We are also finalizing the accompanying amendments to establish authority for HHS to conduct compliance reviews to confirm QHP issuer compliance with the federal APTC, CSR, and user fee standards.

We received public comments on the proposed updates and policies regarding the application of federal APTC, CSR, and user fee requirements to issuers in State Exchanges and SBE-FPs. The majority of the comments we received to this section were also made to the sections regarding HHS's enforcement of the applicable federal APTC, CSR, and user fee

²⁵⁸ The applicable federal standards for APTC and CSRs are found in part 156, subpart E, which apply to QHP issuers participating in all Exchanges types (FFEs, State Exchanges, and SBE-FPs). The applicable federal standards for user fees are found in 45 CFR 156.50, which apply to QHP issuers in FFEs and SBE-FPs.

standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements (§ 156.480(c)(6)); subpart I – enforcement remedies in the Exchanges, available remedies, and scope (§ 156.800); and the bases and process for imposing CMPs in the Exchanges (§ 156.805). We respond to these parallel comments in the bases and process for imposing CMPs in the Exchanges (§ 156.805) preamble section below. However, we received some comments that were specific to this section, suggesting ways for HHS to coordinate with State Exchanges and SBE-FPs to address non-compliance by QHP issuers with applicable federal APTC, CSRs, and user fee standards. The following is a summary of these comments and our responses.

Comment: Commenters emphasized that HHS should collaborate with State Exchanges and SBE-FPs and keep them informed of and involved in HHS's audits of QHP issuers that operate in their respective State Exchange or SBE-FP. They noted that State Exchanges and SBE-FPs should also be informed of upcoming issuer audits and compliance reviews, as well as audit and compliance review findings, including any amounts recouped by HHS and any enforcement action taken against issuers in their states. These commenters offered specific suggestions for how HHS could collaborate with State Exchanges and SBE-FPs. One commenter stated that HHS should provide technical assistance to the state and coordinate with the state on corrective action required of any issuers in the state, if necessary. Another commenter asked that HHS reconsider the role of State Exchanges in audits and revise the audit process accordingly. This commenter suggested creating one audit process for FFE issuers and a different one for State Exchange and SBE-FP issuers, and further suggested HHS could consider creating different processes for State Exchange and SBE-FP issuers, as well as different processes among State Exchanges, as necessary.

Response: HHS generally intends its approach to audits, compliance reviews, and enforcement activities of issuers to be collaborative processes with issuers, states, State Exchanges, and SBE-FPs. HHS will continue to coordinate with State Exchanges and SBE-FPs,

including notifying State Exchanges and SBE-FPs when an audit or compliance review involves an issuer in their state. Additionally, HHS will also consider taking a different approach for conducting APTC, CSR, and user fee audits and compliance reviews for State Exchange issuers, such that HHS more closely involves State Exchanges in the process, to the extent possible and appropriate based on the specific State Exchange and the circumstances involved. This includes HHS considering how best to coordinate APTC, CSR, and user fee audits for State Exchange issuers with existing independent external audit activities that State Exchanges are required to conduct annually, under 45 CFR 155.1200, that cover similar or related Exchange functions such as eligibility determinations, enrollments, and the reporting of eligibility and enrollment data to HHS. State Exchanges are required to report the results of these external audits to HHS and establish corrective action plans for findings, which are jointly monitored by the State Exchange and HHS. In addition, HHS will continue to work with State Exchanges and SBE-FPs to enforce the applicable federal APTC, CSR, and user fee standards, as detailed in the below section on bases and process for imposing CMPs in the Exchanges (§ 156.805).

We appreciate commenters' suggestions and agree that HHS may provide technical assistance to the state and coordinate with the state on corrective action required of any issuers in the state, if necessary, to help guide collaboration efforts with State Exchanges and SBE-FPs with respect to ensuring issuer compliance with federal APTC, CSR, and user fee standards and audits. We intend to consider the various recommendations for potential enhancements to the process for HHS audits and compliance reviews of federal APTC, CSR, and user fee standards, including potential ways to further enhance the collaboration with state regulators, State Exchanges, and SBE-FPs. However, as explained in the proposed rule, the proposed updates were intended to build on the existing framework established in the second Program Integrity Rule and clarify HHS's authority with respect to oversight and enforcement of compliance with federal APTC, CSR, and user fee standards in State Exchange and SBE-FP states.²⁵⁹ We also

²⁵⁹ See 78 FR 65077 and 65078.

remind stakeholders that the APTC, CSR,²⁶⁰ and user fee programs are federal funds, and the focus of these audits will be on issuer compliance with applicable federal standards.

HHS will consider recommendations to enhance the QHP issuer audit and compliance review processes to take into consideration existing audit activities that HHS requires State Exchanges to conduct annually under § 155.1200, the variation between FFE, SBE-FP, and State Exchange issuers, as well as the variation among issuers participating in the different State Exchanges. In all cases, HHS will continue to collaborate with the State Exchange or SBE-FP to enforce the applicable federal APTC, CSR, and user fee standards. Further, one of the goals of these amendments is to ensure the timely and accurate completion of audits of federal funds under the APTC, CSR, and user fee programs. Therefore, based on our experience to date conducting 2014 benefit year CSR audits, to ensure the protection of federal funds and compliance with applicable federal requirements, HHS will generally lead the efforts to audit compliance with federal APTC, CSR, and user fee standards (where applicable) under § 156.480(c).

After consideration of the comments received on these proposals, we are finalizing the provision to apply the same audit requirements to QHP issuers participating in SBE-FP states as for QHP issuers participating in FFE and State Exchange states as proposed. As such, QHP issuers in SBE-FP states will be required to comply with HHS audits and compliance reviews under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees. We are also finalizing the APTC, CSR, and user fee audit requirements at § 156.480(c), as well as HHS's authority to impose CMPs on issuers in State Exchanges and SBE-FPs when the State Exchange or SBE-FP fails to substantially enforce the applicable federal APTC, CSR, and user fee standards at §§ 156.800 and 156.805.

²⁶⁰ The CSR program was 100 percent federal funds prior to October 2017, when CSR payments to issuers were discontinued due to lack of a Congressional appropriation.

b. Audits and Compliance Reviews of APTC, CSRs, and User Fees (§ 156.480(c))

In prior rulemaking, we codified authority for HHS to audit an issuer that offers a QHP in the individual market through an Exchange to assess compliance with the requirements of part 156, subpart E.²⁶¹ We also previously codified general authority for HHS to periodically audit a QHP issuer's financial records related to its participation in an FFE.²⁶² Recently, HHS completed the audits for the 2014 benefit year CSR payments. During these audits, HHS encountered challenges working with some issuers. Specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion and receiving data in a format that is readily usable for purposes of conducting the audit. As such, similar to the proposals related to audits of issuers of reinsurance-eligible plans and risk adjustment covered plans discussed earlier in the proposed rule, we proposed to amend § 156.480(c) to provide more clarity around the issuer requirements for APTC, CSR, and user fee audits. The proposed amendments codify more details about the audit process and clarify issuer obligations with respect to these audits, including what it means to comply with an audit and the consequences for failing to comply with such requirements. Additionally, we proposed to amend § 156.480(c) to also capture and clarify HHS's ability to audit FFE and SBE-FP user fees and the accompanying issuer requirements for such audits. As such, we proposed to rename § 156.480, "Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, and User Fee Programs." HHS currently reviews compliance with applicable federal user fee standards when conducting APTC audits because the same data is used for both purposes; as such, we explained, there would be minimal increased burden as a result of these proposals.

We also proposed several amendments to § 156.480(c) to expand the oversight tools available to HHS beyond traditional audits to also provide authority for HHS to conduct

²⁶¹ 78 FR 65077 and 65078.

²⁶² See 45 CFR 156.705(a)(1). Also see 78 FR 65078 and 65079.

compliance reviews of QHP issuers to assess compliance with the applicable federal APTC, CSR, and user fee standards. We explained that these proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would be conducted to confirm QHP issuer compliance with the federal APTC, CSR, and user fee standards in subpart E of part 156 and 45 CFR 156.50 for user fees, as applicable, and they would generally extend to QHP issuers participating in all Exchanges.²⁶³ A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.²⁶⁴ For example, HHS may require an issuer to submit data pertaining to specific data submissions. We explained that we believed this flexibility is necessary and appropriate to provide HHS a mechanism to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. We further noted that we intend to continue our collaborative oversight approach and coordinate with State Exchanges and SBE-FPs to ensure QHP issuer compliance with the applicable standards in part 156, subpart E and 45 CFR 156.50.

First, we proposed to rename § 156.480(c) to “Audits and Compliance Reviews” to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate QHP issuer compliance with the applicable federal APTC, CSR, and user fee standards. We similarly proposed to update the introductory language in § 156.480(c) to incorporate a reference to HHS compliance reviews. As amended, § 156.480(c) would provide that HHS or its designee may audit and perform compliance reviews to assess whether an issuer that offers a QHP in the individual market through an Exchange is in

²⁶³ HHS does not intend to conduct user fee compliance reviews of QHP issuers participating in State Exchanges that do not rely on the Federal platform. Such reviews would be limited to QHP issuers participating in FFE and SBE-FP states.

²⁶⁴ See 78 FR 65100.

compliance with the applicable requirements of subpart E, part 156, and 45 CFR 156.50. We proposed to capture in a new sentence in the amended § 156.480(c) that HHS would conduct these compliance reviews consistent with the standards set forth in 45 CFR 156.715. As detailed earlier in this preamble, these oversight tools would be available to HHS to evaluate compliance by QHP issuers participating in all Exchanges with the applicable federal APTC, CSR, and user fee standards.

Second, we proposed to add new § 156.480(c)(1) to establish notice and conference requirements for these audits. Proposed new paragraph (c)(1) states that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an QHP issuer under § 156.480(c). Under proposed paragraph (c)(1)(i), HHS proposed to codify that all audits would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Third, HHS proposed to add new paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (c)(2)(i), we proposed to require the issuer to ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section. In new proposed paragraph (c)(2)(ii), we proposed to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (c)(1)(i). For example, for CSR audits, HHS may request that QHP issuers provide a re-adjudicated claims data extract for the selected sample of policies to verify accuracy of the re-adjudication process and reported amounts (this would include verification of all elements necessary to perform accurate re-adjudication) and a data extract containing incurred claims for the selected sample of policies to verify accuracy of actual amount the enrollee(s) paid for EHBs via an Electronic File Transfer. As another example, for APTC

audits, issuers may be asked to provide data to validate and support APTC payments received for the applicable benefit year.

Fourth, under proposed § 156.480(c)(2)(iii), HHS proposed to require that issuers respond to any audit notices, letters, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We explained that we believe that the proposed requirements in paragraph (c)(2) are necessary and appropriate to ensure the timely completion of audits and to protect the integrity of the APTC, CSR, and user fee programs and the payments made thereunder.

Fifth, recognizing that there may be situations that warrant an extension of the timeframes under paragraph (c)(2)(ii) or (iii), as applicable, we proposed to also add a new paragraph (c)(2)(iv) to establish a process for an issuer to request an extension. To request an extension, we proposed to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraph (c)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and the good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

Sixth, under § 156.480(c)(3), HHS proposed that it would share its preliminary audit findings with the issuer, and further proposed that the issuer would then have 30 calendar days to respond to such findings in the format and manner as specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary audit findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. HHS proposed under paragraph (c)(3)(i) that if the

issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. In new proposed paragraph (c)(3)(ii), if the issuer timely responds and disputes the preliminary audit findings within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

Seventh, HHS proposed to add a new section at § 156.480(c)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer would be required to comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We noted that the actions set forth in the final audit report could require an issuer to return APTC or CSRs or make additional user fee payments. HHS further proposed that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

If an issuer fails to comply with the audit requirements set forth in new proposed § 156.480(c), HHS proposed in paragraph (c)(5)(i) that HHS would notify the issuer of payments received that the issuer has not adequately substantiated, and in new proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. Therefore, the continued failure to respond to or cooperate with an audit under paragraph (c) and provide the necessary information to substantiate the payments made could result in HHS recouping up to 100 percent of the APTC or CSR payments made to an issuer for the benefit year(s) that are the subject of the audit.

We clarified in the proposed rule that APTC and CSR amounts recovered by HHS as a result of an audit under § 156.480(c) would be paid to the U.S. Treasury. We further noted that

user fee amounts recovered by HHS as a result of an audit under § 156.480(c) would be paid to the ACA Marketplace user fee program collection account.

Lastly, HHS proposed to add a new paragraph (c)(6) to § 156.480 to codify HHS's ability to enforce the applicable federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements. In instances where HHS enforces compliance with the applicable APTC, CSR, and user fee standards with respect to QHP issuers participating in State Exchanges or SBE-FPs, HHS proposed to use the same standards and processes as outlined in §§ 156.805 and 156.806 for QHP issuers participating in an FFE with respect to the imposition of CMPs. This would include the proposed extension of the process outlined in § 156.901, *et seq.*, for the QHP issuer to appeal the imposition of CMPs. For a discussion of the framework and proposed accompanying penalties for non-compliance in situations where HHS is responsible for enforcement of these requirements, see the following discussion of proposed changes to §§ 156.800 and 156.805.

We sought comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes and processes for issuers to respond to audit notices and requests for information and for issuers to request extensions of those timeframes, and the proposals related to HHS's authority to enforce compliance with the federal APTC, CSR, and user fee requirements if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements. We are finalizing these provisions as proposed, with slight modifications to certain audit timelines in response to comments stating that issuers need more time during audits to provide complete and accurate data. HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit, rather than the proposed 15 calendar days. If HHS determines the need for a corrective action plan as the result of an audit, the issuer must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar days. As noted in the above sections on audits of issuers of reinsurance-eligible plans and risk adjustment

covered plans (§§ 153.410(d) and 153.620(c)), these modified timeframes apply across the parallel HHS audit provisions for reinsurance, risk adjustment, APTC, CSR, and user fee audits.

We also clarify that we will recoup monies owed due to a finding as the result of a reinsurance, risk adjustment, APTC, CSR, or user fee audit using the same method with which we collect all debts. That is, we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt.

We received public comments on the proposed updates to audits and compliance reviews of federal APTC, CSR, and user fee standards (§ 156.480(c)). The majority of the comments we received to the proposed updates outlined in this section were also made to the sections regarding audits and compliance reviews of issuers of reinsurance-eligible plans (§ 153.410(d)) and audits and compliance reviews of issuers of risk adjustment covered plans (§ 153.620(c)). We respond to all of these parallel comments in this section. As noted above, the comments we received to the proposed § 156.480(c)(6) were also made to the sections regarding the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156.480), enforcement remedies in the Exchanges (§ 156.800), and bases and process for imposing CMPs in the Exchanges (§ 156.805). We summarize and respond to those parallel comments in the § 156.805 preamble section below.

The following is a summary of the parallel general comments we received to all of the audits and compliance review proposals in this rule and the specific comments on the proposed updates to § 156.480(c), with the exception of the comments submitted on § 156.480(c)(6), and our responses.

Comment: Several commenters supported the various audit and compliance review proposals, noting that they will clarify expectations and requirements, ensure compliance, and protect federal funds. Other commenters opposed the proposals and asked HHS to put audit standards in guidance, rather than regulation, as this would maintain flexibility and make it easier for HHS to revise requirements and improve the audit process.

Response: We agree that these provisions will provide clarity for issuers and better facilitate compliance with any HHS audits, as well as enable HHS to protect federal funds. Many of the provisions are merely a codification of the current audit processes that have been used in prior reinsurance, APTC, CSR, and user fee audits.²⁶⁵ We maintain our commitment to working with issuers to meet these requirements, and we note that we proposed and are finalizing a process to allow issuers to submit written requests to extend certain audit response deadlines with good cause.²⁶⁶

We also note that, to provide clear and enforceable standards, we proposed and are finalizing the codification of these procedures in regulation.

Comment: A few commenters requested more flexibility regarding the data format issuers must use.

Response: In order for HHS to complete an audit, we must receive data from issuers in a set format communicated to issuers at the audit entrance conference to be able to analyze data from all issuers using the same procedures. As we explained in the proposed rule, HHS experienced difficulties receiving requested audit data in a format that is readily usable for purposes of conducting the audit. Therefore, we believe it is appropriate and necessary to codify in regulation a requirement that issuers must submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS. For example, for CSR audits, HHS may request that QHP issuers provide a re-adjudicated claims data extract for the selected sample of policies to verify accuracy of the re-adjudication process and reported amounts (this would include verification of all elements necessary to perform accurate re-adjudication) and a data extract containing incurred claims for the selected sample of policies to verify accuracy of actual amount the enrollee(s) paid for EHBs via an Electronic File Transfer. For APTC audits, issuers may be asked to provide data to validate and support APTC

²⁶⁵ HHS has not yet conducted any risk adjustment audits under 45 CFR 153.620(c).

²⁶⁶ See 45 CFR 153.410(d)(2)(iv), 156.620(c)(2)(iv) and 156.480(c)(2)(iv), which we are finalizing as proposed.

payments received for the applicable benefit year. To reduce burden on issuers, we anticipate being able to continue to review compliance with applicable federal user fee standards when conducting APTC audits because the same data is used for both purposes. We also note that if more time is needed to compile the requested data in the required format, an issuer could request an extension under §§ 153.410(d)(2)(iv), 156.620(c)(2)(iv), or 156.480(c)(2)(iv), as applicable.

Comment: Many commenters requested longer timelines for audit notice and issuer responses to HHS to the various audit requests, noting that issuers would need more time than what was proposed in order for issuers to provide complete and accurate data or otherwise respond to HHS requests. Some commenters requested that HHS provide 30 calendar days advance notice of its intent to conduct an audit, rather than the proposed 15 calendar days. Other commenters requested that HHS set the deadline for issuers to submit corrective action plans at either 45 or 60 calendar days, rather than the proposed 30 calendar days. One commenter requested that HHS set the initial data submission deadline at 45 calendar days and subsequent request deadlines at 30 calendar days, rather than the proposed 30 calendar days and 15 calendar days, respectively. Other commenters asked that HHS permit extensions to the timeframes set forth for these audits. A couple of commenters asked that HHS be more timely with respect to performing audits.

Response: We appreciate these comments and acknowledge that our experience with 2014 benefit year CSR and reinsurance audits demonstrated that issuers need sufficient time to provide complete and accurate data for audits, and we acknowledge that some issuers will face difficulties in retrieving and properly formatting data from prior benefit years. We also recognize that it would be beneficial for all stakeholders if issuers could receive more advance notice of an upcoming audit or compliance review to allow the issuer (and HHS or its designee) to begin preparation and coordination efforts earlier. Therefore, in response to these comments, we are modifying the timeframe in § 156.480(c)(1) to require HHS to provide at least 30 calendar days advance notice of its intent to conduct an APTC, CSR, or user fee audit rather than the proposed

15 calendar days. Similarly, we are modifying the timeframes in §§ 153.410(d)(1) and 153.620(c)(1) to require HHS to provide at least 30 calendar days advance notice of its intent to conduct an audit of a reinsurance-eligible plan or a risk adjustment covered plan, respectively, rather than the proposed 15 calendar days. As for the time allowed to provide the initial audit submission, HHS will continue to maintain the 30 calendar day deadline. HHS believes that in order to complete the audit process in a timely manner and based on prior audit experience, after giving issuers 30 calendar days advance notice of the audit, which is 15 days longer than initially proposed, an additional 30 days to provide the initial data submission for the audit is more than reasonable. We note that as stated in §§ 153.410(d)(2)(iv), 153.620(c)(2)(iv), and 156.480(c)(2)(iv), we proposed and are finalizing the flexibility for issuers to seek extensions for reinsurance, risk adjustment, and APTC, CSR, and user fee audit-related requests from HHS under §§ 153.410(d)(2)(ii) or (iii), 153.620(c)(2)(ii) or (iii), and 156.480(c)(2)(ii) or (iii), respectively, but believe the 30 calendar day timeline to provide the initial audit submission strikes the appropriate balance and will allow HHS to work with issuers to ensure the proper data is provided and the audit can be conducted and completed more efficiently. We are also maintaining the 30 calendar day timeframe for issuers to respond to preliminary audit findings.²⁶⁷ We similarly believe that this timeframe strikes the appropriate balance and ensures these audits can be completed more efficiently.

Additionally, in response to comments suggesting a 45 calendar day deadline for issuers to provide written corrective action plans rather than the proposed 30 calendar day deadline, we will finalize a 45 calendar day timeframe to submit a corrective action plan if an audit results in the inclusion of a finding in the final audit report, rather than a 30 calendar day timeframe, at § 153.410(d)(4)(i) for reinsurance program audits, § 153.620(c)(4)(i) for risk adjustment program audits, and § 156.480(c)(4)(i) for APTC, CSR, and user fee audits. We are persuaded by these comments and agree that issuers would benefit from the extension of this timeframe because the

²⁶⁷ See 45 CFR 153.410(d)(3), 153.620(c)(3), and 156.480(c)(3).

development of a corrective action plan may require a significant amount of coordination and discussion between HHS, the state (if applicable), and the issuer in order to finalize the appropriate corrective action(s) and plan for implementation. Therefore, as finalized, the issuer must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar days, for those situations where one or more findings are included in the final audit report.²⁶⁸

HHS makes every effort to conduct audits in an efficient and timely manner and will continue to do so. The audit proposals addressed in the proposed rule and this final rule are aimed at making the audit process more efficient so that audits may be completed in a shorter length of time. However, HHS is flexible and willing to work with issuers who keep us informed of their progress but may need more time. Therefore, as we proposed, we are also finalizing at § 153.410(d)(2)(iv) for reinsurance program audits, § 153.620(c)(2)(iv) for risk adjustment program audits and § 156.480(c)(2)(iv) for APTC, CSR, and user fee audits that issuers may request an extension to certain audit deadlines by submitting a written request to HHS within the applicable timeframe(s)²⁶⁹ for reinsurance program audits, risk adjustment program audits, and APTC, CSR, and user fee audits. For all of these audits, the written request would have to detail the reasons for the extension request and the good cause in support of the request and must be submitted within the applicable timeframe for responding to the HHS request.

Comment: A few commenters asked that HHS avoid audits during the annual open enrollment period (OEP) to allow issuers to focus their resources on enrollment and other OEP activities.

²⁶⁸ We also reiterate that an issuer, acting in good faith, can submit an extension request if it finds additional time is needed to respond to certain HHS requests stemming from these audits. See 45 CFR 153.410(d)(2)(iv), 156.620(c)(2)(iv) and 156.480(c)(2)(iv).

²⁶⁹ As proposed and finalized, issuers may request to extend the following timeframes: (1) for reinsurance program audits, the timeframes under 45 CFR 153.410(d)(2)(ii) or (iii); (2) for risk adjustment audits, the timeframes under 45 CFR 153.620(c)(2)(ii) or (iii); and (3) for APTC, CSR, and user fee audits, the timeframes under 45 CFR 156.480(c)(2)(ii) or (iii).

Response: HHS agrees that issuers should devote their resources to enrollment during the OEP and will take this request into consideration in scheduling the start of future audits. Because audits are an ongoing process and the timeline for completion is not always fixed, it may not be possible to entirely avoid overlap between audit activities and OEP, but HHS will work with issuers to avoid situations where audit activities could undermine or otherwise negatively impact issuers' ability to focus on enrollment during the annual OEP. For example, we are finalizing the proposal to permit issuers to request an extension to certain audit deadlines at §§ 153.410(d)(2)(iv), 153.620(c)(2)(iv), and 156.480(c)(2)(iv), for audits of issuers of reinsurance-eligible plans, audits of issuers of risk adjustment covered plans, and audits of the APTC, CSR, and user fee programs, respectively. We clarify that an issuer who has made good faith efforts to otherwise comply with HHS audit requests could submit such an extension request if it needed more time with respect to completing its audit activities under 45 CFR 153.410(d)(2)(ii) or (iii) for reinsurance program audits, 45 CFR 153.620(c)(2)(ii) or (iii) for risk adjustment program audits, and 45 CFR 156.480(c)(2)(ii) or (iii) for APTC, CSR, and user fee audits, due to the overlap with the annual OEP.

Comment: Some commenters asked that HHS rely on existing audits rather than adding new audits and audit requirements.

Response: In response to these comments, we clarify that HHS is not adding new audit authority for reinsurance-eligible plans, risk adjustment covered plans, or APTC, CSRs, and user fees. Rather, we are expanding the existing authority to codify more details about audit activities to set clear expectations, facilitate compliance and enforcement, protect federal funds, and maintain program integrity. The standards being codified comprise best practices and procedures that HHS has established in audit entrance conferences and incorporates lessons learned from audits of the reinsurance and CSR programs for the 2014 benefit year, and audits of the APTC program for the 2014 through 2017 benefit years. HHS's audit regulations in these areas were

finalized in earlier rulemakings.²⁷⁰ We are, however, finalizing new authority to permit HHS to conduct compliance reviews to ensure compliance with applicable reinsurance, risk adjustment, and federal APTC, CSR, and user fee standards. As explained elsewhere in this rule and in the proposed rule, we believe this additional authority related to compliance reviews is necessary and appropriate in order to provide HHS a mechanism to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question.

Comment: A few commenters noted that the proposed compliance reviews would place an increased burden on states and issuers.

Response: We generally disagree that the proposed compliance review proposals would place an increased burden on states. Of particular note, these proposals, which we are finalizing in the introductory language to §§ 153.410(d), 153.620(c), and 156.480(c), involve situations where HHS – rather than the states – would conduct a review to confirm an issuer’s compliance with the applicable federal program standards and requirements. While there may be some increased burden associated with coordination between HHS and the states, any such increased burden on states should be minimal. We further note that the purpose of the proposed HHS compliance reviews, as stated in the preamble section above and in the proposed rule, is to confirm QHP issuer compliance with the applicable federal reinsurance, risk adjustment, or APTC, CSR, and user fee standards. These compliance reviews are intended to be less burdensome than audits of compliance with requirements under the applicable programs, and may further be targeted at a specific potential error and conducted on an ad hoc basis.²⁷¹ For example, HHS may require an issuer to submit data pertaining to specific data submissions. We believe this flexibility is necessary and appropriate to provide HHS a mechanism to address

²⁷⁰ See, for example, 78 FR at 65077 – 65078; 79 FR at 13770 – 13771 and 13781 – 13782.

²⁷¹ See 78 FR 65100.

situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. HHS intends to conduct compliance reviews sparingly and will provide advance notice of a compliance review to the issuer being reviewed and the applicable state regulator(s), State Exchange, or SBE-FP. Therefore, while we acknowledge that there will be some burden on issuers associated with these compliance reviews, we believe the benefits for all stakeholders associated with finalizing this additional oversight tool outweighs such burdens as it allows for a more targeted approach to ensure compliance with applicable federal requirements.

Comment: One commenter asked that HHS only conduct CSR audits of issuers for the time during which HHS made advance CSR payments; that is, the 2014 benefit year through September of the 2017 benefit year.

Response: At this time, HHS is beginning audits of the 2015 and 2016 benefit year of CSR payments. HHS has not yet made a determination as to whether or not CSR audits will be conducted for the 2017 benefit year and beyond.

Comment: One commenter supported HHS recouping up to 100 percent of applicable APTC or CSR payments. Another commenter stated that HHS should use the normal debt collection process of netting and then invoicing issuers to collect any remaining debt amount owed as a result of audit findings and that the proposed 100 percent recoupment of APTC, CSR, reinsurance, and risk adjustment payments was unreasonable.

Response: If an issuer is not able to adequately substantiate the APTC, CSR, reinsurance, or risk adjustment payments it received from HHS during the course of an audit, HHS has an obligation to recoup federal funds and protect the integrity of these programs. We further note that issuers have separate record retention requirements that must be met and the documents required to be maintained can be utilized to substantiate payment.²⁷² Therefore, it is appropriate

²⁷² See §§ 153.410(c), 153.620(b), 156.480(a), and 156.705.

and necessary for HHS to recoup any APTC, CSR, reinsurance, or risk adjustment payments made to issuers that were not adequately substantiated by the issuer during the course of an audit. This may include up to 100 percent recoupment if the issuer is entirely unable to substantiate the payments it received that are the subject of the audit. However, we anticipate that this situation would be extremely rare, and HHS would work with the issuer to provide reasonable opportunities for the issuer to substantiate the payments it received under these programs. As with all debt collection for the ACA financial programs, HHS will follow the process set forth in § 156.1215 to collect any amounts owed as a result of an audit under 45 CFR 153.410(d), 153.620(c) and 156.480(c). We affirm that we therefore intend to leverage the existing netting and debt collection process to recoup monies owed due to a finding as the result of these audits. That is, to recoup an amount identified as owed as a result of an audit under 45 CFR 153.410(d), 156.620(c), and 156.480(c), we will first net using the process set forth in 45 CFR 156.1215, and will then invoice issuers for the remaining debt (if any is owed).

Comment: A couple of commenters requested more information on the proposed updates to audits and compliance reviews of APTC, CSRs, and user fees under § 156.480(c) and, more specifically, the proposed inclusion of user fees as part of the audit framework in this regulation. One commenter wanted more information on the user fee audits referred to in this proposal. Another commenter wanted HHS to publish audit protocols with information on audit requirements, file layouts, submission requirements, and source documentation for the § 156.480(c) audits.

Response: As stated in the preamble section above, HHS currently reviews compliance with applicable federal user fee standards in 45 CFR 156.50 when conducting APTC audits, because the same data is used to audit both APTC and user fees. Audits of APTC and user fees are conducted simultaneously using the same data; as such, there is minimal increased burden as a result of the amendments being finalized in this rule to consolidate the user fee audit standards alongside the APTC and CSR audit standards in § 156.480(c).

We further note that HHS currently provides information on audit requirements, file layouts, submission requirements, and source documentation as part of the applicable audit entrance conference. Issuers selected for audit receive this information at the entrance conference, which they are required to attend, and also receive further details on these requirements from HHS via the audit contractor. Guidance documents related to APTC audit requirements are also available on REGTAP.²⁷³

After consideration of the comments on the audit proposals in §§ 153.410(d), 153.630(c), and 156.480(c), we are finalizing these provisions as proposed, with slight modifications to certain audit timelines in response to comments stating that issuers need more time during audits to provide complete and accurate data and to provide written corrective action plans. HHS will provide at least 30 calendar days advance notice of its intent to conduct a reinsurance, risk adjustment, APTC, CSR, or user fee audit, rather than the proposed 15 calendar days. If an audit results in the inclusion of a finding in the final audit report, the issuer must provide a written corrective action plan to HHS for approval within 45 calendar days of the issuance of the final audit report, rather than the proposed 30 calendar days.

We also clarify that we will recoup monies owed due to a finding as the result of a reinsurance, risk adjustment, APTC, CSR, or user fee audit using the same method with which we collect all ACA financial program debts. That is, we will first net using the process set forth in 45 CFR 156.1215, and we will then invoice issuers for the remaining debt.

7. Subpart I—Enforcement Remedies in Federally-Facilitated Exchanges; Available remedies; Scope. (§ 156.800)

We proposed to rename Subpart I to “Enforcement Remedies in the Exchanges,” and to make other amendments to clarify that HHS has the ability to impose CMPs when it is enforcing the applicable federal requirements in part 156, subpart E and 45 CFR 156.50 for user fees,

²⁷³ See, for example, “CMS Issuer Audits of the Advance Payments of the Premium Tax Credit,” April 1, 2019. Available at (login required): https://www.regtap.info/uploads/library/CMS_PPFMG_EA_CMSAPTCAudits_5CR_040119.pdf.

regardless of whether the Exchange is established and operated by a state (including a regional Exchange or subsidiary exchange) or by HHS.²⁷⁴ As explained in prior rulemaking, in states where there is a State Exchange, the State Exchange has primary enforcement authority over QHP issuers participating in the Exchange and ensuring compliance with the applicable federal APTC, CSR, and user fee standards.²⁷⁵ However, consistent with the framework established in section 1321(c)(2) of the ACA, HHS has authority to step in to enforce requirements related to the operation of Exchanges and the offering of QHPs through Exchanges if a state fails to do so.^{276,277} As such, in the case of a determination by the Secretary that a State Exchange or SBE-FP has failed to enforce or substantially enforce a federal requirement (or requirements) related to QHP issuer participation in the individual market Exchange, HHS has authority to step in and enforce QHP issuer compliance with the requirement(s).

Through its cross-reference to section 2723(b) of the PHS Act,²⁷⁸ section 1321(c)(2) of the ACA authorizes the Secretary to impose CMPs for non-compliance with applicable federal Exchange requirements. In the proposed rule, we proposed to codify HHS authority to impose CMPs for non-compliance by QHP issuers that participate or have participated in a State Exchange or SBE-FP in situations where HHS steps in to enforce certain requirements. Specifically, this proposal is focused on ensuring compliance with the standards for APTC, CSR payments, and user fees captured in part 156, subpart E and 45 CFR 156.50. Under this proposal, we would apply the bases and follow the processes for imposing CMPs as set forth in § 156.805, would send a notice of non-compliance as set forth in § 156.806, and would extend the administrative review and appeal process set forth in § 156.901, *et seq.* to provide a forum for

²⁷⁴ Exchange models include State Exchanges, SBE-FPs, and FFEs. HHS does not intend to use this authority to impose CMPs related to user fee standards applicable to QHP issuer participating in State Exchanges.

²⁷⁵ See the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR 65077 and 65078.

²⁷⁶ *Ibid.*

²⁷⁷ Section 1321(c)(2) of the ACA provides that the enforcement framework established in section 2736(b), which was renumbered 2723(b), of the PHS Act shall apply to the enforcement of requirements established in section 1321(a)(1).

²⁷⁸ While the text of section 1321(c)(2) of the ACA cites to section 2736(b) of the PHS Act, this PHS Act provision was renumbered a second time to section 2723(b) as part of the technical and conforming amendments in the ACA. See section 1562(c)(13)(C) of the ACA.

QHP issuers in State Exchanges and SBE-FPs to appeal the imposition of CMPs by HHS. We did not propose to extend the authority to decertify a QHP under § 156.800(a)(2) for non-compliance by QHP issuers in State Exchanges or SBE-FPs; QHP de-certification in State Exchanges or SBE-FPs would remain an available enforcement tool for the applicable Exchange. We explained that this proposal is not intended to duplicate state enforcement efforts, as HHS generally depends on State Exchanges and SBE-FPs to enforce federal requirements applicable to QHPs and QHP issuers participating in the state's individual market Exchange. The proposed amendments are instead intended to establish an enforcement framework to capture situations where HHS is responsible for enforcement if a State Exchange or SBE-FP fails to do so and is focused on the federal APTC, CSR, and user fee requirements in order to protect federal funds.

We also explained that we expected that states that established a State Exchange or SBE-FP will enforce all applicable federal requirements applicable to QHPs and QHP issuers participating in Exchanges, including the applicable APTC, CSR, and user fee standards captured in part 156, subpart E and 45 CFR 156.50. However, to address situations where a State Exchange or SBE-FP fails to enforce these federal Exchange requirements, consistent with the framework established in section 2723(b) of the PHS Act, we proposed that if HHS determines that a State Exchange or SBE-FP lacks authority or has otherwise failed to substantially enforce the requirements captured in part 156, subpart E or 45 CFR 156.50, HHS would step in to enforce these requirements with respect to QHP issuers participating in the State Exchange or SBE-FP. Once this determination is made, HHS would become responsible for enforcement of these provisions and would take appropriate action to ensure QHP issuer compliance with the applicable requirement(s),²⁷⁹ and may impose CMPs, if appropriate. To more clearly capture HHS's authority to impose CMPs in these situations, we proposed to amend the introductory

²⁷⁹ As detailed earlier, when HHS is responsible for enforcement of these Exchange requirements, we are finalizing the proposal to extend authority for HHS to pursue a compliance review under § 156.480(c), consistent with the framework establish in § 156.715, to confirm compliance with federal APTC, CSR, and user fee requirements by a QHP issuer participating in a State Exchange or SBE-FP.

sentence to § 156.800(a) to replace the current references to the “Federally-facilitated Exchange” with references to “an Exchange.” We also proposed to amend § 156.800(b) to remove the word “only” from the sentence describing the scope of HHS sanctions with respect to QHP issuers participating in FFEs and to add a new second sentence that affirms HHS authority to impose CMPs for non-compliance with the applicable requirements in part 156, subpart E and 45 CFR 156.50 by QHP issuers participating in State Exchanges and SBE-FPs.

We also noted that we intend to continue our collaborative enforcement approach and would coordinate our actions with state efforts to avoid duplication and to streamline oversight of the administration of APTC, CSRs, and user fees. We solicited comments for how HHS can collaborate with State Exchanges and SBE-FPs to proactively address non-compliance with applicable federal requirements and share compliance tools regarding APTC, CSRs, and user fees. We are finalizing the proposals to (1) amend the introductory sentence to § 156.800(a) to replace the current references to the “Federally-facilitated Exchange” with references to “an Exchange,” and (2) amend § 156.800(b) to remove the word “only” from the sentence describing the scope of HHS sanctions with respect to QHP issuers participating in FFEs and to add a new sentence that affirms HHS authority to impose CMPs for non-compliance with the applicable requirements in part 156, subpart E and 45 CFR 156.50 by QHP issuers participating in State Exchanges and SBE-FPs.

We received public comments on the proposed updates to Subpart I—Enforcement Remedies in Federally-Facilitated Exchanges; Available remedies; Scope (§ 156.800). The comments we received to this section were also made to the sections regarding the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156.480), HHS enforcement of the applicable federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements (§ 156.480(c)(6)), and the bases and process for imposing CMPs in the Exchanges (§ 156.805), and we responded

to all of these parallel comments in the bases and process for imposing CMPs in the Exchanges (§ 156.805) preamble section below.

After consideration of the relevant comments, we are finalizing the amendments to § 156.800 as proposed. As detailed further in the below section on the bases and process for imposing CMPs in the FFEs, we also clarify that we intend to leverage this authority to pursue enforcement and the imposition of CMPs in State Exchange and SBE-FP states where HHS is responsible for enforcement in a targeted manner with a focus on egregious or repeated occurrences of QHP issuer noncompliance with the applicable APTC, CSR, and user fee standards that are discovered as the result of audits and the State Exchange or SBE-FP fails to substantially enforce the applicable standard(s). We further note that we did not propose and are not finalizing any substantive changes related to the enforcement framework applicable to QHP issuers participating in FFEs. The below section on bases and process for imposing CMPs in the Exchanges discusses this point in further detail.

8. Bases and Process for Imposing Civil Money Penalties in Federally-facilitated Exchanges (§ 156.805)

We also proposed to amend § 156.805 to more clearly reflect HHS's authority to impose CMPs due to non-compliance with respect to the applicable federal APTC, CSR, and user fee standards against a QHP issuer participating in a State Exchange or SBE-FP. Under this proposal, we would use the same bases and process currently captured in § 156.805 for imposing CMPs on QHP issuers participating in an FFE. More specifically, in § 156.805, we proposed renaming this section to "Bases and process for imposing CMPs in the Exchanges," and also proposed to amend the introductory language in § 156.805(a) to use the words "an Exchange," instead of "Federally-facilitated Exchange," to more clearly capture HHS's authority to impose CMPs on QHP issuers participating in State Exchanges and SBE-FPs who fail to comply with the applicable requirements in part 156, subpart E or § 156.50 in situations where HHS is responsible for enforcement. We similarly proposed to modify § 156.805(a)(5)(i) where the

reference to “HHS” currently appears to also incorporate a reference to “an Exchange” to clarify that all QHP issuers must avoid intentionally or recklessly misrepresenting or falsifying APTC, CSR, and user fee information to both HHS and Exchanges, regardless of whether HHS or a state operates the Exchange. We proposed this amendment to clarify that HHS has authority to impose CMPs against QHP issuers participating in State Exchanges and SBE-FPs who misrepresent or falsify APTC, CSR, and user fee information provided to HHS in situations where HHS is responsible for enforcement of the requirements in part 156, subpart E or § 156.50, including when HHS is performing an audit or compliance review under § 156.480(c). If HHS seeks to use this authority to impose CMPs against a QHP issuer participating in a State Exchange or SBE-FP, we proposed the issuer would have the opportunity to appeal the CMPs following the existing framework for administrative hearings in § 156.901, *et seq.*

Finally, we proposed to add a new paragraph (f) to § 156.805 to capture in this regulation details on the circumstances requiring HHS enforcement of the applicable requirements in part 156, subpart E and § 156.50. Consistent with the framework established in section 2723(b) of the PHS Act and section 1321(c) of the ACA, we propose in new § 156.805(f)(1) that HHS’s authority to enforce in these situations would be limited to situations where the State Exchange or SBE-FP notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, *et seq.* that a State Exchange or SBE-FP is failing to substantially enforce these requirements.²⁸⁰ In new proposed § 156.805(f)(2), we proposed to affirm that when HHS is responsible for enforcement in these circumstances, HHS may impose CMPs on an issuer in the State Exchange or SBE-FP, in accordance with the bases and process set forth in this section. As noted in the proposed rule, this includes the ability for a QHP issuer in a State Exchange or SBE-FP to appeal the imposition of CMPs by HHS following the existing framework for administrative hearings in § 156.901, *et seq.*

²⁸⁰ See, for example, 45 CFR 150.203.

We proposed that HHS would apply the same process HHS uses to determine when a state is failing to substantially enforce PHS Act requirements in determining whether a State Exchange or SBE-FP is substantially enforcing the applicable federal APTC, CSR, and user fee standards. More specifically, we proposed that if an audit of a QHP issuer in a State Exchange or SBE-FP demonstrates the State Exchange or SBE-FP's failure to enforce the applicable federal APTC, CSR, and user fee standards, HHS would investigate the State Exchange or SBE-FP's enforcement and follow the process set forth in 45 CFR 150.207 if necessary. We proposed that if HHS receives or obtains information (including information discovered through an audit) that a State Exchange or SBE-FP may not be enforcing the applicable requirements in part 156, subpart E, or 45 CFR 156.50, HHS may initiate the process described in 45 CFR 150.207 to determine whether the State Exchange or SBE-FP is failing to substantially enforce these requirements. Mirroring the process set forth in 45 CFR 150.207 for making determinations regarding substantial enforcement of PHS Act requirements, HHS would follow the procedures in §§ 150.209 through 150.219 to determine if a State Exchange or SBE-FP is failing to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50. If HHS believes there is a reasonable question whether there has been a failure to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50, HHS would send a notice, as described in 45 CFR 150.213, identifying the applicable requirement(s) that allegedly have not been substantially enforced to the proper State Exchange or SBE-FP officials using the process outlined in 45 CFR 150.211. We proposed that, following the process described in 45 CFR 150.215, HHS may extend, for good cause, the time the State Exchange or SBE-FP has for responding to the notice, such as if there is an agreement between HHS and the State Exchange or SBE-FP that there should be a public hearing on the State Exchange or SBE-FP's enforcement, or evidence that the State Exchange or SBE-FP is undertaking expedited enforcement activities. Using the process described in 45 CFR 150.217, if at the end of the extension period HHS determines that the State Exchange or SBE-FP has not established to

HHS's satisfaction that it is substantially enforcing the applicable requirements, we proposed that HHS would consult with the appropriate State Exchange or SBE-FP officials, notify the State Exchange or SBE-FP of its preliminary determination that the State Exchange or SBE-FP has failed to substantially enforce the requirements and that the failure is continuing, and permit the State Exchange or SBE-FP a reasonable opportunity to show evidence of substantial enforcement. If, after providing notice and a reasonable opportunity for the State Exchange or SBE-FP to show that it has corrected any failure to substantially enforce, HHS finds that the failure to substantially enforce has not been corrected, HHS would notify the State Exchange or SBE-FP of its final determination using the process described in 45 CFR 150.219. Therefore, we proposed that after a determination that a State Exchange or SBE-FP is not or cannot substantially enforce the applicable requirements in part 156, subpart E or § 156.50, HHS could impose CMPs on issuers in the State Exchange or SBE-FP if there is cause for such imposition. HHS would also provide a notice of non-compliance, consistent with § 156.806, to QHP issuers in State Exchanges or SBE-FPs prior to imposing CMPs.

We explained that we sought to work collaboratively with State Exchanges and SBE-FPs for any topics of mutual concern and oversight activities where possible. We also sought comment to this proposal, the proposed updates to § 156.805, and ways in which HHS and state authorities can efficiently and effectively enforce federal standards related to APTC, CSRs, and user fees.

We also proposed that if the changes to §§ 156.800 and 156.805 were finalized as proposed, we would also amend § 156.903 such that an administrative law judge's authority also extends to CMPs imposed against QHP issuers in State Exchanges and SBE-FPs under § 156.805. Specifically, we proposed to amend § 156.903(a) to extend the provision to also include State Exchanges and SBE-FPs so that the ALJ has the authority, including all the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and

impartial hearing on the record and to issue an initial decision concerning HHS's imposition of a CMP on a QHP offered in a FFE, State Exchange, or SBE-FP.

We received public comments on the proposed updates to bases and process for imposing civil money penalties in Federally-facilitated Exchanges (§ 156.805). The majority of the comments we received to this section were also made to the proposals regarding HHS enforcement of the applicable federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements (§ 156.480(c)(6)), the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156.480), and the enforcement remedies in the Exchanges, available remedies, and scope (§ 156.800). The following is a summary of these comments and our responses.

Comment: One commenter supported the proposed updates to the application of requirements to issuers in State Exchanges and SBE-FPs (§ 156.480(c)), the enforcement remedies in the Exchanges, available remedies, and scope (§ 156.800), and the bases and process for imposing CMPs in the Exchanges and the accompanying updates to § 156.805. Several commenters opposed the proposal and asked for more information on the process by which HHS would determine that a State Exchange or SBE-FP is failing to substantially enforce the applicable requirements. A few commenters asked for more information on the types of issues that would result in HHS commencing the process to determine whether a State Exchange or SBE-FP is failing to substantially enforce the applicable federal requirements.

Response: We anticipate that an imposition of a CMP by HHS on QHP issuers in State Exchanges and SBE-FPs through these proposed updates should be very rare, as we have not yet imposed a CMP on any QHP issuer in any of the APTC, CSR, user fee, reinsurance, or risk adjustment audits we have conducted to date. We also anticipate that it would be rare for an issuer to repeatedly fail to comply with the applicable federal APTC, CSR, and user fee standards, as well as for the State Exchange or SBE-FP to fail to substantially enforce these standards after being notified by HHS of such potential non-compliance as the result of an audit.

We reiterate our commitment to working with issuers, State Exchanges, and SBE-FPs to evaluate issuer non-compliance with the applicable federal APTC, CSR, and user fee standards and intend to resort to leveraging the authority for HHS to step in and take the appropriate enforcement action in State Exchange and SBE-FP states, including imposing CMPs, in very limited situations where we have evidence or information suggesting that the state is not enforcing and QHP issuers in that state are not complying with the applicable federal standard(s) for APTC, CSRs, and/or user fees. We did not propose and are not finalizing any substantive changes related to the enforcement framework applicable to QHP issuers participating in FFEs. The purpose of these proposals is to codify the authority for HHS to step in and enforce the applicable standards, including the ability to impose CMPs, if necessary should the situation arise. We emphasize that the amendments to §§ 156.800 and 156.805 are targeted to provide HHS authority to step in when there are egregious or repeated occurrences of QHP issuer non-compliance with the applicable APTC, CSR, and user fee standards that are discovered as the result of multiple audits and the State Exchange or SBE-FP is also failing to substantially enforce the applicable standard(s). We therefore anticipate such situations will be rare.

In response to comments, we offer the following example of a situation in which HHS could begin the process of making a determination that a State Exchange or SBE-FP is failing to substantially enforce the applicable APTC, CSR, and user fee requirements. If HHS discovers, as the result of an audit, that an issuer in a State Exchange or SBE-FP failed to comply with a federal APTC requirement, it would inform the State Exchange or SBE-FP and the issuer of this finding and set forth required corrective actions for the issuer to take. If HHS then discovers in the following year's audit of this same issuer that the issuer has not taken the corrective actions and is continuing to fail to comply with the requirement, HHS would again inform the State Exchange or SBE-FP and the issuer of this repeated finding, and ask the State Exchange or SBE-FP to take the appropriate enforcement action against the issuer for noncompliance. If the State Exchange or SBE-FP repeatedly fails to enforce the applicable requirement across multiple

benefit years and the issuer continues to have an audit finding related to this non-compliance across multiple benefit years, HHS would begin the process of making a determination that the State Exchange or SBE-FP is failing to substantially enforce that requirement. We reiterate our commitment to working with State Exchanges and SBE-FPs, and we confirm that this policy is narrowly targeted at egregious or repeated occurrences of QHP issuer non-compliance with the applicable APTC, CSR, and user fee standards evaluated through audits of these programs. We also reiterate that the above is an illustrative example. Consistent with the statutory framework outlined in section 1321(c) of the ACA, and as reflected in the amendments we are finalizing to §§ 156.800 and 156.805, HHS may step in to enforce applicable federal APTC, CSR, and user fee standards in other situations where there is evidence or information suggesting that the State Exchange or SBE-FP is failing to do so.²⁸¹ Once HHS makes a determination that a State Exchange or SBE-FP is failing to substantially enforce the applicable federal requirements, HHS may pursue CMPs against issuers for non-compliance under §§ 156.800 and 156.805 in appropriate situations.

The process by which HHS proposed and is finalizing to determine whether a State Exchange or SBE-FP is failing to substantially enforce the applicable APTC, CSR, and user fee requirements mirrors the process set forth in 45 CFR 150.207 for making determinations regarding a state's substantial enforcement of PHS Act requirements. As detailed above, the process involves HHS sending notice to the proper State Exchange or SBE-FP officials; permits extending the time the State Exchange or SBE-FP has for responding to the notice; requires consulting with the appropriate State Exchange or SBE-FP officials; and mandates that HHS notify the State Exchange or SBE-FP of HHS's preliminary determination that the State Exchange or SBE-FP has failed to substantially enforce the requirement(s) and that the failure is continuing. Only after HHS goes through the process and makes a determination that the State

²⁸¹ Consistent with the statute, HHS may also leverage this authority in situations where there is evidence or information suggesting the State Exchange or SBE-FP is failing to substantially enforce other federal Exchange requirements.

Exchange or SBE-FP is substantially non-enforcing applicable APTC, CSR, and user fee requirements, and the State Exchange or SBE-FP fails to address the identified concerns, would HHS have authority to begin the process to impose a CMP on a QHP issuer in a State Exchange or SBE-FP state pursuant to 45 CFR 156.805 for their non-compliance.

Comment: Numerous commenters stated that this proposal would improperly usurp the role of states in enforcing these requirements in their own Exchanges.

Response: We disagree that this approach improperly usurps the role of states in enforcing requirements within their own Exchanges, as the process outlined above provides ample opportunity for State Exchanges and SBE-FPs to take action and demonstrate substantial enforcement at multiple points in the process before HHS assumes enforcement authority. Additionally, pursuant to section 1321(c) of the ACA, HHS has the statutory authority and responsibility to enforce federal requirements when the State Exchange or SBE-FP fails to do so and is instructed to follow the framework set forth in section 2723(b) of the PHS Act when doing so. This authority necessarily includes the ability to impose CMPs on issuers for non-compliance with APTC, CSR, or user fee requirements in states where HHS is responsible for enforcement. As explained above and in the proposed rule, our experience with APTC, CSR, and user fee audits led us to propose these amendments to ensure a framework is in place for HHS to address non-compliance and protect federal funds when a State Exchange or SBE-FP fails to substantially enforce federal standards and QHP issuers in those states are failing to comply with applicable federal APTC, CSR, and user fee requirements. We again reiterate our commitment to working with State Exchanges and SBE-FPs to address non-compliance by QHP issuers operating in their respective states with applicable federal APTC, CSR, and user fee standards. As noted earlier, the purpose of these proposals is to codify in regulation HHS's authority to step in and enforce federal requirements and protect federal funds when the applicable state authority fails to do so. Further, we also note that we intend to focus our enforcement efforts on egregious

or repeated occurrences of QHP issuer non-compliance with the applicable APTC, CSR, and user fee standards evaluated through an audit of these programs.

Comment: Several commenters emphasized that HHS should work with State Exchanges and SBE-FPs to enforce the applicable federal requirements. One commenter requested that HHS monitor State Exchange and SBE-FP remediation efforts to address issuer non-compliance before imposing CMPs.

Response: HHS will work with State Exchanges and SBE-FPs to enforce the applicable requirements, as set forth above. We intend for audits, compliance reviews, and enforcement activities to be collaborative processes with states, State Exchanges, and SBE-FPs, where possible. For instance, HHS will consider the recommendations for how to leverage existing audit activities that HHS requires State Exchanges to conduct under § 155.1200 to collaborate with State Exchanges on identifying instances of issuer non-compliance or monitoring State Exchange or issuer remediation activities. HHS will follow the process for determining that a State Exchange or SBE-FP is failing to enforce or failing to substantially enforce these requirements, consistent with the framework set forth in §§ 150.209 through 150.219. As described above, this process follows a collaborative approach and permits HHS to monitor State Exchange and SBE-FP remediation efforts as the Exchange works to address issues identified by HHS. It also provides ample opportunity for the State Exchange or SBE-FP to show that it has corrected (or is working to correct) any failure to substantially enforce before HHS makes a final determination about whether a State Exchange or SBE-FP is failing to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50. It is only after HHS goes through the process and makes a determination that the State Exchange or SBE-FP is substantially failing to enforce these requirements, and the State Exchange or SBE-FP fails to address the identified concerns, that HHS would have authority to begin the process to impose a CMP on a QHP issuer in a State Exchange or SBE-FP state pursuant to 45 CFR 156.805 for their

non-compliance.²⁸² As detailed in the above illustrative example, we intend to work closely with the applicable state authorities and monitor state remediation efforts to address issuer non-compliance before HHS starts the process to step in to enforce the applicable federal requirements or impose CMPs.

Comment: One commenter requested that we link the proposed audit provisions for the APTC, CSR and user fee programs and HHS's authority to recoup payments to the regulations codified in 45 CFR part 150 to more directly link this recoupment authority to the PHS Act.

Response: Consistent with the authority in section 1321(c) of the ACA, HHS proposed and is finalizing the proposals to establish and clarify its authority to audit and conduct compliance reviews of all QHP issuers who receive APTC or CSRs or pay user fees under § 156.480(c) regardless of Exchange type. We are also finalizing provisions that reference the process in 45 CFR 150.201, *et. seq.*, so HHS can leverage the existing, known process in situations where HHS has evidence or other information that the State Exchange or SBE-FP is failing to substantially enforce the applicable requirements found at 45 CFR 156, subpart E for APTC and CSRs and 45 CFR 156.50 for user fees. We believe this is an appropriate and adequate link of the audit requirements in § 156.480(c) to the regulations codified in 45 CFR part 150, which implement section 2723(b) of the PHS Act.²⁸³ We confirm that our current intention is to apply this new framework to situations involving egregious or repeated occurrences of QHP issuer non-compliance with the applicable APTC, CSR, and user fee standards evaluated through the audits of these programs. However, consistent with the statutory framework outlined in section 1321(c) of the ACA, and as reflected in the amendments we are finalizing to §§ 156.800 and 156.805, HHS may step in to enforce applicable federal APTC, CSR, and user fee standards in situations where there is evidence or information suggesting that the State Exchange or SBE-

²⁸² If a State Exchange or SBE-FP notifies HHS that it has not enacted legislation to enforce or that it is not otherwise enforcing the applicable federal requirement(s), HHS may step in to enforce the requirement(s) in that state at that time. See 45 CFR 150.203(a).

²⁸³ While the APTC, CSR, and user fee statutory provisions are codified outside of the PHS Act, section 1321(c) of the ACA applies the PHS Act enforcement framework to the enforcement of the federal Exchange requirements.

FP is failing to do so.²⁸⁴ As detailed above, we believe it is appropriate and necessary for HHS to recoup amounts that were not adequately substantiated by the issuer during the course of an audit.²⁸⁵

After consideration of the comments received on these proposals, we are finalizing the proposed amendments to § 156.805 to describe the bases and process by which HHS may determine that a State Exchange or SBE-FP is failing to substantially enforce the applicable federal APTC, CSR, and user fee standards and subsequently impose CMPs on these State Exchange or SBE-FP issuers as proposed.

9. Subpart J – Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947)

We proposed to change the title to subpart J, removing the reference to “in Federally-Facilitated Exchanges” to make clear it applies to QHP issuers participating in any Exchange type to align with accompanying proposed changes outlined above to §§ 156.800 and 156.805. We also proposed several procedural changes to provisions in subpart J of part 156 related to administrative hearings consistent with the amendments discussed in the preamble to part 150. These proposed procedural changes are intended to align with the Departmental Appeals Board’s current practices for administrative hearings to appeal CMPs. Specifically, we proposed changes that would remove requirements to file submissions in triplicate and instead require electronic filing. This change is reflected in the proposed amendments to the definition of “Filing date” in § 156.901, to the introductory text in § 156.927(a), and to the service of submission requirements captured in paragraph (b). We also proposed to allow for the option of video conferencing as a form of administrative hearing by amending the definition of “Hearing” in § 156.901 and to the requirements outlined in § 156.919(a) related to the forms for the hearing, § 156.941(e) related to

²⁸⁴ Consistent with the statute, HHS may also leverage this authority in situations where there is evidence or information suggesting the State Exchange or SBE-FP is failing to substantially enforce other federal Exchange requirements.

²⁸⁵ Issuers have separate record retention requirements that must be met and the documents required to be maintained can be utilized to substantiate payment. See §§ 153.410(c), 153.620(b), 156.480(a), and 156.705.

prehearing conferences, and § 156.947(a) related to the record of the hearing. Finally, we proposed to update § 156.947 to allow the ALJ to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date. We sought comment on these proposals.

We received the same public comments on the proposed updates to Subpart J – Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947) and the parallel proposed updates to Part 150, Administrative Hearings, for the parallel amendments made to reflect the Departmental Appeals Board’s current practices for administrative hearings to appeal CMPs. We summarized and responded to these comments in the above preamble section on Part 150 Administrative Hearings. We did not receive comments on the proposed change to the title to subpart J, removing the reference to “in Federally-Facilitated Exchanges”. After consideration of the comments on the proposed amendments to §§ 156.901, 156.927, 156.931 and 156.947 and the title to subpart J, we are finalizing these amendments as proposed.

10. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

Section 1311(c)(3) of the ACA directs the Secretary of HHS to develop a quality rating for each QHP offered through an Exchange, based on quality and price. Section 1311(c)(4) of the ACA directs the Secretary to establish an enrollee satisfaction survey that will assess enrollee satisfaction with each QHP offered through the Exchanges with more than 500 enrollees in the prior year.

Based on this authority, HHS finalized rules in May 2014 to establish standards and requirements related to QHP issuer data collection and public reporting of quality rating information in every Exchange.²⁸⁶ To balance HHS’s strategic goals of empowering consumers through data, minimizing cost and burden on QHP issuers, and supporting state flexibility, HHS developed a phased-in approach to establishing quality standards for Exchanges and QHP

²⁸⁶ See 79 FR 30240 at 30352. Also see 45 CFR 155.1400, 155.1405, 156.1120 and 156.1125.

issuers, collecting and reporting quality measure data, and displaying quality rating information across the Exchanges. Since 2015, we have collected clinical quality measure data and enrollee experience survey measure data and generated quality ratings to provide reliable, meaningful information about QHP quality performance data across Exchanges. In addition, since 2016, select states²⁸⁷ with FFEs and State Exchanges have displayed QHP quality rating information as a tool for consumer decision-making while shopping for health insurance coverage in an Exchange. Beginning with the open enrollment period for plan year 2020, we displayed the QHP quality rating information for all Exchanges that used the HealthCare.gov platform, including the FFEs and SBE-FPs. State Exchanges that operated their own eligibility and enrollment platform were similarly required to display QHP quality ratings beginning with the open enrollment period for plan year 2020, but had some flexibility to customize the display of the QHP quality rating information.²⁸⁸

Through valuable feedback from the QRS and QHP Enrollee Survey Call Letter process and continued engagement with health plan issuer organizations, health care quality measurement experts, state representatives, consumer advocates and other stakeholders, we continued to learn about populations buying insurance coverage across the Exchanges and about areas of improvement for these programs. We also continued to assess potential refinements to the QRS rating methodology and the QHP Enrollee Survey to prioritize strategies to improve value for consumers and to reduce the burden of quality reporting.

As part of the 2020 QRS and QHP Enrollee Survey Call Letter process, we received many comments requesting that we remove levels of the QRS hierarchy to help streamline and improve consumer understanding of the quality rating information. While we did not propose

²⁸⁷ Prior to the PY2020 nationwide display of quality rating information, states that displayed QHP quality rating information included California, Colorado, Connecticut, Maryland, Michigan, Montana, New Hampshire, New York, Rhode Island, Virginia, Washington, and Wisconsin.

²⁸⁸ “CMS Bulletin on display of QRS star ratings and QHP Enrollee Survey results for QHPs offered through Exchanges (often called the Health Insurance Marketplace),” August 15, 2019. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf>.

amendments to the QRS or to the QHP Enrollee Survey as part of the proposed rule, we sought comment on the removal of one or more levels of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We previously described the general overall framework for the QRS, including details on the hierarchical structure of the measure set and the elements of the QRS rating methodology.²⁸⁹ Currently, the QRS measures are organized into composites, domains, and summary indicators that serve as a foundation for the rating methodology and scores are calculated at every level of the hierarchy using specific scoring and standardization rules, as described in the annual QRS and QHP Enrollee Survey Technical Guidance.²⁹⁰ We noted in the proposed rule that we believe that a simplified QRS hierarchy would support alignment with other CMS quality reporting programs and help the overall quality score be more reflective of the performance of individual survey and clinical quality measures within the QRS. For example, the Medicare Part C & D Star Ratings framework consists of measures, domains, summary ratings and an overall rating.²⁹¹ In addition, we noted that we believe a simplified hierarchy, in combination with additional methodology modifications we considered (for example, explicit weights at the measure level) will help stabilize ratings across years.²⁹² We sought comment specifically on which level or levels of the QRS hierarchy should be removed (for example, the composite level or the domain level).

In addition, to further support transparency of QHP quality data and to empower stakeholders including consumers, states, issuers and researchers with valuable information related to enrollee experience with QHPs, we proposed to make the full QHP Enrollee Survey

²⁸⁹ See, for example, 78 FR 69418.

²⁹⁰ “The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2021,” September 2020. Available at <https://www.cms.gov/files/document/quality-rating-system-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf>.

²⁹¹ “Medicare 2019 Part C & D Star Rating Technical Notes,” October 10, 2019. Available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10-2019.pdf>.

²⁹² CMS anticipates continuing to propose methodology refinements to the QRS and QHP Enrollee Survey through the Call Letter process.

results publicly available in an annual PUF. Currently, we post on HealthCare.gov some enrollee experience results in the form of a quality rating for Member Experience and Plan Administration that make up part of the overall rating for QHPs.²⁹³ The Member Experience rating is based on a select number of survey measures from the QHP Enrollee Survey. The Plan Administration rating is based on a select number of survey measures and clinical quality measures. To promote transparency of data to the public, we already post QRS PUFs every year for QHP issuers operating in all Exchange types that were eligible to receive quality ratings. As we stated in the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule, we have been considering different ways to make QHP quality data, including QHP Enrollee Survey results, publicly available and accessible to researchers, consumer groups, states and other entities.²⁹⁴ Similar to the QRS PUFs, we proposed to post a QHP Enrollee Survey PUF annually, beginning with the 2021 QHP Enrollee Survey results and during the 2022 open enrollment period, that would include the score and proportion of responses (for example, the percentage of respondents answering “Never” or “Sometimes”) for every survey question and composite as well as demographic information such as employment status, race and ethnicity, and age at the reporting unit and national level to facilitate data transparency.

We solicited comment on this proposal to post a QHP Enrollee Survey PUF annually and on potential changes to the QRS hierarchy.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the removal of levels of the QRS hierarchy to align with other CMS quality reporting programs and to increase the ability for the overall quality score to be more reflective of the performance of individual quality measures in the QRS. Several commenters specifically supported the removal of the composite and domain levels of

²⁹³ A rating for Medical Care is the other component of the overall rating.

²⁹⁴ 79 FR at 30311.

the QRS hierarchy. Some commenters requested the timeframe of when modifications to the QRS hierarchy would take effect.

Response: We agree that with removal of levels of the QRS hierarchy, there will be closer alignment with other CMS quality reporting programs such as Medicare Part C & D Star Ratings. We also agree that by removing the composite level and domain level from the QRS hierarchy, we will be simplifying the hierarchy and the anticipated, improved understanding of the overall quality scores will be more reflective of the individual measures' performance that contributes to those scores. Thus, after consideration of the comments received, we are finalizing the removal of the composite level and domain level from the QRS hierarchy. We intend to clarify the timeframe for these modifications to the QRS hierarchy in the QRS and QHP Enrollee Survey Technical Guidance for 2022, which would affect the 2022 ratings year for Plan Year 2023.

Comment: One commenter urged CMS to route any changes related to the QRS hierarchy through the QRS Technical Expert Panel (TEP), which is comprised of subject matter experts who will be able to give feedback on the proposed changes to the methodology and weigh proposed changes against any other QRS methodology changes that are being considered. Another commenter urged CMS to continue examining the QRS hierarchy to understand impact to weight redistribution before finalization of removal of a level of the QRS hierarchy (that is, with either the composite or domain level removed) and to identify evidence that the streamlined hierarchy is effective in mitigating data or calculation concerns encountered in other rating systems.

Response: We appreciate the commenters' suggestions and requests for clarification related to the removal of one or more levels of the QRS hierarchy. We confirm that we discussed the potential removal of levels of the QRS hierarchy with the QRS TEP in 2017 and based on testing using previous years' data, CMS believes that the removal of the composite and domain levels and the explicit weights at the summary indicator will balance the weight of individual

measures on the global score. In addition, removal of both the composite and domain levels of the QRS hierarchy will not result in issues with weight redistribution because we intend to retain the explicit weights at the summary indicator level to align with the amount of measures within each summary indicator. CMS intends to retain the summary indicators to remain in alignment with other CMS quality reporting programs (that is, Medicare Part C & D Star Ratings) and intends to continue to assign a weight of 2/3 (66.67%) to the Clinical Quality Management summary indicator, and a weight of 1/6 (16.67%) to the Enrollee Experience and Plan Efficiency, Affordability, & Management summary indicators. This weighting structure reflects the approximate percentage of measures in each summary indicator. CMS believes that the removal of both the composite and domain levels of the QRS hierarchy will mitigate stakeholders' main concern with data and calculations in the QRS (that is, the implicit weighting). We also clarify that we continue to explore the potential of introducing new methods of assessing performance at the measure level and have proposals available in the current Draft 2021 Call Letter²⁹⁵.

Comment: A few commenters requested further clarifications and considerations including urging CMS to grant additional flexibility to states in the display of the star ratings and noted that technical details around quality rating information display are provided to State Exchanges too late for states to update system requirements.

Response: We clarify that per the 2021 Payment Notice final rule, State Exchanges have increased flexibility and can make determinations about display of quality rating information to best meet the needs of their population. As part of the 2021 Payment Notice final rule, we codified in §§ 155.1400 and 155.1405 the option for State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information provided by HHS or to display HHS-provided quality rating information with certain state-

²⁹⁵ "Draft 2021 Call Letter for the Quality Rating System and QHP Enrollee Experience Survey," February 2021. Available at <https://www.cms.gov/files/document/draft-2021-call-letter-qrs-qhp-enrollee-survey.pdf>.

specific customizations for their QHPs to best reflect local priorities or information.²⁹⁶ We also clarify that refinements to the QRS hierarchy do not change the display requirements for State Exchanges that operate their own eligibility and enrollment platforms. State Exchanges that operate their own eligibility and enrollment platforms continue to have the flexibility to make certain state-specific customizations related to the display of quality ratings or to maintain the display of the overall rating and three summary indicator ratings in alignment with HealthCare.gov. We understand that guidance posted by CMS related to the display of quality rating information on HealthCare.gov may be communicated too late for states to update their system requirements. Thus, CMS will continue to provide flexibility and technical assistance to State Exchanges as necessary and appropriate, and will continue to discuss timelines for implementation with any State Exchanges that are unable to meet applicable quality rating information display requirements.

Comment: A majority of commenters strongly agreed with the proposal to make QHP Enrollee Survey results publically available in an annual PUF to increase transparency and consumer satisfaction and to assist states in monitoring the quality of insurance coverage offered through the Exchanges. One commenter asked for clarification related to the reasons underlying CMS' proposal to make QHP Enrollee Survey results publically available.

Response: We agree that a PUF that includes results from the full QHP Enrollee Survey will improve transparency of enrollee experience information across Exchanges. We stated in the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule that we have been considering different ways to make QHP quality data, including QHP Enrollee Survey results, publicly available and accessible to researchers, consumer groups, states and other entities.²⁹⁷ We believe that providing this QHP quality data aligns with other CMS quality reporting programs, including Medicare Advantage and Prescription Drug Plan (PDP) Consumer

²⁹⁶ 85 FR 29214 through 29216.

²⁹⁷ 79 FR 30311.

Assessment of Healthcare Providers and Systems (CAHPS) and CAHPS for the Merit-based Incentive Payment System (MIPS), that publically report survey scores and help beneficiaries, issuers, researchers and others better understand the experiences of the individuals and families that are enrolled in different health plans and programs.

Comment: A few commenters who supported the proposal to make QHP Enrollee Survey results publicly available urged CMS to require additional information related to quality measure data submitted to an Exchange by survey vendors and issuers. One commenter requested that CMS permit states to collect a de-identified survey response file that includes demographic information needed to appropriately case-mix adjust the results to facilitate a better understanding of opportunities for improvement. Another commenter urged CMS to require stratification of at least some quality measures by race, ethnicity, primary language, and disability to address highly prevalent conditions in communities of color.

Response: We appreciate the requests for CMS to require that additional quality measure information to be submitted to an Exchange by survey vendors and issuers. CMS does permit HHS-approved survey vendors to share de-identified person-level data sets of QHP Enrollee Survey questions with States, but to protect enrollee confidentiality, survey vendors are prohibited from sharing person-level demographic data. CMS case-mix adjusts QHP Enrollee Survey response data using variables including the following: general health rating, mental health rating, chronic conditions/medications, age, education, survey language, help with the survey, and survey mode. CMS intends to include case-mix adjusted scores for QHP Enrollee Survey questions and composites at the reporting unit level in the PUF. In general, CMS is supportive of stratification of at least some quality measures by areas such as race, ethnicity, primary language, disability, and potentially other social determinants of health. We intend to include demographic information such as age, education level, employment, race and ethnicity in the QHP Enrollee Survey PUF to facilitate transparency of this data at the reporting unit level. CMS is not requiring additional quality measure data at this time because we understand that

stratification requires QHP issuers to have specific member-level data and anticipates that the incorporation of stratification for quality measures may take time. CMS is committed to advancing health equity and addressing health and health care disparities. As part of this objective, CMS is exploring the stratification of measures by sociodemographic factors including race and ethnicity. CMS will follow industry standards around the type of data needed to report stratified measure rates.

Comment: A few commenters mentioned they do not support publishing QHP Enrollee Survey results at this time because of a lack of transparency of the information to be included in the PUF, explanatory materials, data definitions and communication strategy that would allow consumers to use this information appropriately in making decisions. One commenter noted that survey results are already displayed through star ratings and that additional results would not be meaningful without sufficient explanation, including cut points.

Response: We clarify that CMS will provide details and materials related to the QHP Enrollee Survey PUF in alignment with other Exchange PUFs and other quality data PUFs, including a data dictionary, an overview of the QHP Enrollee Survey, as well as the definitions of all survey questions and composites. We agree that there are already some survey results displayed on HealthCare.gov in the form of a quality rating for Member Experience, which makes up part of the Overall Rating for QHPs. The Member Experience rating is based on a select number of survey measures from the QHP Enrollee Survey. However, after 4 years of collecting survey measure data, we believe it is important to facilitate transparency of QHP enrollee experience results from the full survey. Similar to the QRS PUF, CMS intends to include responses at the reporting unit level for all survey questions in the annual QHP Enrollee Survey PUF, including those not included in the QRS. The QHP Enrollee Survey PUF will provide results of scoring the QHP Enrollee Survey questions and composites. CMS does not use cut points to calculate the QHP Enrollee Survey scores. We agree that including cut points may

provide more meaning to the QRS results included in the QRS PUF and will consider adding the cut points to the QRS PUFs in the future.

Comment: One commenter noted that the QHP Enrollee Survey results are proprietary and cannot be shared publicly.

Response: We disagree with the assertion that QHP Enrollee Survey results are proprietary. In accordance with section 1311(c)(3) and (c)(4) of the ACA and 45 CFR 155.1400 and 155.1405, all Exchanges have the authority to publicly report QHP quality rating information, including survey results, on their websites to help consumers compare and shop for QHPs. QHP issuers are required to collect survey data and the data is used both by CMS and to inform issuers' internal quality improvement efforts. Similar to the QRS PUF and other Exchange PUFs, CMS will publish the QHP Enrollee Survey PUF on data.healthcare.gov.

Comment: One commenter expressed concerns regarding potential negative impacts on the QHP Enrollee Survey results due to the COVID-19 pandemic, including significant membership fluctuations and membership composition changes.

Response: We recognize the concern regarding negative impacts of the COVID-19 pandemic on the QHP Enrollee Survey results. We note that CMS proposed, in the Draft 2021 Call Letter, temporary QRS methodology changes to mitigate the impact of COVID-19 on QRS ratings. We also clarify that CMS will review all quality measure data that is submitted for 2021 QRS ratings, including survey measure data, and make determinations regarding display of quality rating information and release of quality data PUFs after the scoring and rating process and prior to the 2022 open enrollment period for the individual Exchange.

Comment: Some commenters noted general concerns about the QHP Enrollee Survey, including burdensome survey length and appropriate survey timing resulting in lower response rates and lower reliability on certain questions. Before publicly reporting full survey results, the commenter recommended that CMS consider removing questions that have reliability below 0.70, remove questions outside of the health plan's control, remove any survey questions with

less than 100 responses in the denominator from reporting and remove the demographic items from the survey that duplicate information submitted at enrollment and rely on the 834 enrollment file instead.

Response: We understand the commenter's concerns and provide the following clarifications about the QHP Enrollee Survey. CMS aims for statistically high reliability (generally, 0.70 or above) for the survey questions and composites. In some cases, there are topic areas critical to inform consumer understanding and issuer quality improvement that may not consistently meet high reliability thresholds but remain important indicators of quality (for example, topics such as enrollee experience with their provider and health care). Given the importance of transparency around these topics, CMS anticipates including all survey questions within the PUF. CMS also anticipates monitoring reliability over time and will consider refinements to this approach, if needed. CMS expects the PUF will include the number of responses to each question and the number of completed surveys to assist users with analyzing survey data. We also clarify that we continue to assess the length and timing of the QHP Enrollee Survey. We believe that currently, the QHP Enrollee Survey generally aligns with the length and timing of other CAHPS surveys (for example, Medicare Advantage PDP CAHPS survey, Medicare Advantage Only CAHPS) and similarly, posting of an annual QHP Enrollee Survey PUF would align with other quality reporting programs. In addition, we rely on QHP issuers to populate the sample frame files used to field the QHP Enrollee Survey. QHP issuers' access to demographic data collected in the 834 enrollment file can vary based on the type of Exchange in which the issuer operates (that is, State Exchanges or Federally-facilitated Exchanges). Furthermore, CMS collects demographic data through the QHP Enrollee Survey that may not be included in the 834 enrollment file.

After consideration of all public comments received, we are finalizing the proposal to make the full QHP Enrollee Survey results publicly available in an annual PUF, and the removal of the composite level and domain level from the QRS hierarchy. We intend to clarify the

timeframe for the removal of the composite and domain levels of the QRS hierarchy in the QRS and QHP Enrollee Survey Technical Guidance for 2022, which would affect the 2022 ratings year for Plan Year 2023.

11. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice, we established provisions related to the confirmation and dispute of payment and collection reports. These policies were finalized under the assumption that all issuers that receive APTC would generally be able to provide these confirmations or disputes automatically to HHS. However, HHS has found that many issuers prefer to research payment errors and use enrollment reconciliation and disputes to update their enrollment and payment data, and may be unable to complete this research and provide confirmation or dispute of their payment and collection reports within 15 days, the timeline established by the 2014 Payment Notice.

In the 2021 Payment Notice, we amended § 156.1210(a) to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow all issuers who receive APTC more time to research, report, and correct inaccuracies through other channels. The longer timeframe also allows for the processing of reconciliation updates, which may resolve potential disputes. Additionally, at § 156.1210, we removed the requirement at paragraph (a) that issuers actively confirm payment accuracy to HHS each month, as well as the language in paragraph (b) regarding late filed inaccuracies. Instead, we amended paragraph (b) to require an annual confirmation from issuers that the amounts identified in the most recent payment and collections report for the coverage year accurately reflect applicable payments owed by the issuer to the federal government and the payments owed to the issuer by the federal government, or that the issuer has disputed any identified inaccuracies, after the end of each payment year, in a form and manner specified by HHS.

Since finalizing these changes, HHS's experience has shown that some data inaccuracies reasonably will be identified after the 90-day reporting window. For example, issuers might

receive notification of an eligibility appeal adjudication after the 90-day submission window. Additionally, some issuers are directed to update their enrollment and payment data after an HHS data review or audit which may occur after this 90-day window. In such instances it is in the interest of HHS, states, issuers, and enrollees to accept the late reporting of data inaccuracies. As such, we proposed to amend § 156.1210 by redesignating current § 156.1210(b) to § 156.1210(d) and adding new § 156.1210(b) to establish a process for issuers to report enrollment or payment data changes in these situations.

We clarified that this proposed flexibility would not reduce an issuer's obligation to make a good faith effort to identify and promptly report discrepancies within the 90-day reporting window established under § 156.1210(a). We further explained that issuers could demonstrate good faith by sending regular and accurate enrollment reconciliation files and timely enrollment disputes throughout the applicable enrollment calendar year, making timely and regular changes to enrollment reconciliation and dispute files to correct past errors, and by reaching out to HHS and responding timely to HHS outreach to address any issues identified. With respect to inaccuracies identified after the end of the applicable 90-day period, we proposed to work with the issuer to resolve the inaccuracy if the issuer promptly notifies HHS, in a form and manner specified by HHS, no later than 15 days after identifying the inaccuracy. The failure to identify the inaccuracy in a timely manner in these situations must not have been due to the issuer's misconduct or negligence. For example, issuers must regularly perform monthly enrollment reconciliation as required under § 156.265(f), and should regularly review monthly enrollment reconciliation files so that disputes are submitted in the 90-day reporting window. Disputes submitted after the expiration of the reporting window as a result of an issuer's failure to conduct these activities in a timely manner would not satisfy the good faith standard. We proposed to codify these criteria at new proposed § 156.1210(b)(1) and (2).

Additionally, we proposed to add paragraph (c) to allow the reporting of data inaccuracies after the 90-day period up to 3 years following the end of the plan year to which the

inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is later. We believe this deadline will provide issuers with enough time to report any data inaccuracies discovered after the 90-day submission window, while providing a reasonable end date by which HHS, the State Exchange, issuer and other stakeholders can consider the records for a particular benefit year closed.

We noted that, under section 1313(a)(6) of the ACA, “payments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729, et seq.) if those payments include any Federal funds.” As such if an issuer has an obligation to pay back APTC, the issuer could be liable under the False Claims Act for knowingly and improperly avoiding the obligation to pay. We proposed to codify in § 156.1210(c)(3), that, if a payment error is discovered after the 3-year or end of audit reporting deadline, the issuer is obligated to notify HHS and the State Exchange, as applicable and repay any overpayment. However, HHS will not pay the issuer after the 3-year or end of audit reporting deadline for any underpayments discovered.

We further clarified that the requirements of § 156.1210 apply to all issuers who receive APTC, including issuers in State Exchanges. We sought comment on all aspects of this proposal, including its impact on the State Exchanges’ ability to resolve disputes and report payment adjustments to HHS in this timeframe. We are finalizing the amendments to §§ 156.1210(b) and (c), as proposed, to establish a framework to permit issuers to report data inaccuracies after the 90-day window up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is later. As detailed further below, we are also codifying the clarification we announced in the proposed rule by finalizing conforming amendments to section § 156.1210 to more clearly reflect that these requirements also apply to issuers in state Exchanges. We received public comments on the proposed updates to dispute of HHS payment and collections reports (§ 156.1210). The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the amendments to § 156.1210 which provide issuers the flexibility to identify inaccuracies after the 90-day reporting window within the 3-year or end of audit deadline for reporting identified inaccuracies window. Commenters, including those representing a State Exchange, appreciated HHS's interest in removing unnecessary reporting requirements to reduce administrative burden for issuers, and improving data accuracy, as well as HHS's expressed intention to work cooperatively with issuers that make a good faith effort to comply with these requirements. These commenters also supported the proposed change to reporting timeframes and appreciated the additional time to report payment inaccuracies, while highlighting the importance of maintaining compliance standards.

Response: We agree with commenters that finalizing these provisions will improve data accuracy and reduce administrative burden on issuers by allowing more time to address inaccuracies in enrollment and payment data, while maintaining compliance standards. We are committed to supporting State Exchanges in resolving disputes and reporting payment adjustments in an efficient and timely manner. We are finalizing the proposed amendments to § 156.1210, which will allow the identification of inaccuracies in the monthly payment and collections reports after the 90-day period if the late-identification was not due to the issuer's misconduct or negligence. We are also finalizing the provision that permits the reporting of these inaccuracies up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year after which point the issuer will not be paid for any underpayments that may be discovered. However, if any payment errors are discovered after the applicable deadline, the issuer remains obligated to notify HHS and the State Exchange, or SBE-FP, as applicable, and will be responsible for repaying any identified overpayments. As detailed further below, we are also codifying the clarification we announced in the proposed rule by finalizing conforming amendments to section § 156.1210 to more clearly reflect that these requirements also apply to issuers in State Exchanges. We clarify that these conforming amendments are not intended to change existing requirements or processes

for State Exchanges or their respective issuers. If State Exchange issuers currently work with the State Exchange to review the amounts identified in the payment and collection reports and resolve inaccuracies, they should continue to do so with any identified overpayments being repaid to HHS within the applicable timeframe set forth in § 156.1210. State Exchange issuers who currently work with HHS to review these reports and resolve any inaccuracies under § 156.1210, along with issuers in FFE states, should continue to work with HHS on these matters and should also repay any identified overpayments to HHS within the applicable timeframe(s) set forth in § 156.1210.

Comment: One commenter suggested that HHS make payments to issuers for underpayments discovered after the 3-year or end of audit deadline proposed in § 156.1210(c). Another commenter opposed the 3-year deadline and noted it would prolong the dispute resolution process and the time and work that goes into addressing disputes. This commenter suggested that HHS shorten the timeframe for identifying inaccuracies from 3 years following the end of a plan year to 1 year following the end of a plan year.

Response: The 3-year following the end of the plan year to which the inaccuracy relates or end of HHS audit process for such plan year deadline is intended to provide issuers the flexibility to resolve data inaccuracies encountered after the initial 90-day reporting window, while still encouraging the timely review of enrollment and payment data by providing a date certain for the deadline for identification of such inaccuracies. Based on our experience operating the FFE, we believe shortening this timeframe to one year following the end of a plan year would be insufficient to support the resolution process both for issuers, States, and HHS. For example, the one year timeframe would not align with the submission window for an issuer in a State Exchange time to complete the retroactive State Based Marketplace Inbound (SBMI) payment files, which are submitted up to 3 years after the relevant benefit year. Further, our changes align with the 3-year timeframe established by the IRS. More specifically, 26 U.S.C. 6501 and 26 U.S.C. 6511 state that the amount of any tax imposed shall be assessed within 3 years after the

return was filed. For example, in both the FFE and State Exchanges, a consumer may dispute or amend their insurance coverage by submitting a 1095A update which allows them to amend their taxes up to 3 years. We further note that the 3-year following the end of the plan year to which the inaccuracy relates or end of the HHS audit process for such plan year deadline finalized in this rule does not reduce the issuer's obligation to make a good faith effort to promptly report discrepancies within the 90-day reporting window. In order to encourage all issuers to complete review within the applicable timeframes, HHS reaffirms that it will not make additional payments to issuers for identified underpayments after 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is later.

After consideration of the comments on these proposals, we are finalizing amendments to § 156.1210 which will allow issuers the flexibility to identify data inaccuracies after the 90-day period and report inaccuracies up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year. We are finalizing these amendments as proposed and are codifying the clarification we announced in the proposed rule by finalizing conforming amendments to more clearly reflect that the requirements of § 156.1210 apply to all issuers who receive APTCs, including issuers in State Exchanges by adding a reference to “or the State Exchange (as applicable)” to paragraph (a), the introductory sentence to paragraph (b), paragraphs (b)(1) and (b)(2), as well as paragraph (c)(3).

12. Payment and Collection Processes (§ 156.1215)

In the 2015 Payment Notice, HHS established a monthly payment and collections cycle for insurance affordability programs, user fees, and premium stabilization programs. As discussed elsewhere in this rule, we proposed to eliminate state user fee collection flexibility that HHS had previously offered to states as part of the 2017 Payment Notice²⁹⁸, and proposed

²⁹⁸ See 81 FR at 12317 – 12318.

conforming amendments to remove the reference to “State” governments from paragraph (b).

We sought comment on these proposed amendments.

We received public comments on the proposed updates to dispute of HHS payment and collections processes (§ 156.1215). The following is a summary of the comments we received and our responses.

Comment: The comments received on the proposed updates to payment and collection processes (§ 156.1215) supported the elimination of the state user fee collection flexibility that HHS had previously offered to states in the 2017 Payment Notice, and the conforming amendments to remove the reference to “State” governments from § 156.1215(b).

Response: We believe that updating the payment and collection processes in § 156.1215 to align with the elimination of the unutilized state user fee collection flexibility by striking the reference to “State” will clarify the policy and is an appropriate amendment to make at this time. We appreciate the supportive comments on this proposal.

After consideration of comments received on this proposal, we are finalizing the amendment to § 156.1215(b) as proposed.

13. Administrative Appeals (§ 156.1220)

As detailed earlier in this preamble, we previously established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain ACA programs, including the calculation of risk adjustment charges, payments and user fees. This process also applies to issuer disputes of the findings of a second validation audit (if applicable) as a result of HHS-RADV for the 2016 benefit year and beyond.²⁹⁹ As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the initial validation audit and second validation audit will receive a Second Validation Audit Findings Report and therefore have the right to appeal the second validation audit findings. In this rule, we proposed to amend § 156.1220(a)(1)(vii) to add “if applicable” when discussing an issuer’s

²⁹⁹ See 45 CFR 156.1220(a)(1)(vii).

ability to appeal the findings of the second validation audit to more clearly capture this limitation as part of the regulation, consistent with the existing language at § 153.630(d)(2) and the previously finalized policy. We proposed a similar amendment in this rule to § 153.630(d)(3).

We also proposed amendments to § 156.1220(a)(3) to clarify that the 30-calendar day timeframe to file a request for reconsideration of second validation audit findings (if applicable) or the risk score error rate calculation would be 30 calendar days from the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers. To capture this clarification, we proposed to create a new proposed § 156.1220(a)(3)(ii) to specify the timeframe for filing a request for reconsideration for a risk adjustment payment or charge, including an assessment of risk adjustment user fees. This new proposed regulatory provision maintains the language that establishes a 30 calendar day window for these appeals that begin on the date of notification under § 153.310(e). We also proposed to create a new proposed § 156.1220(a)(3)(iii) to separately address the timeframe for filing a request for reconsideration of second validation audit findings or the risk score error rate calculation and to add the phrase "if applicable" to more clearly capture the limitation on the ability to appeal second validation audit findings. To accommodate these two new proposed paragraphs, we also proposed to amend § 156.1220 to redesignate paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively. We sought comment on these proposals.

The only comment received on the proposed updates to the administrative appeals regulations (§ 156.1220) noted general support of the proposed amendments and accompanying clarifications.

After consideration of comments received on these proposals, we are finalizing the amendments to § 156.1220 as proposed.

F. Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Definitions (§ 158.103)

We proposed to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes.

In the preamble to the proposed rule, we discussed that HHS received numerous comments during the regulatory process of finalizing amendments to § 158.140(b)(1)(i) in the 2021 Payment Notice final rule with respect to reporting prescription drug rebates and other price concessions.³⁰⁰ The commenters requested HHS to codify and align the definition of prescription drug rebates and other price concessions that are reported by issuers for MLR purposes with the definition in section 1150A of the Act, as added by the ACA,³⁰¹ which requires QHP issuers and PBMs to report certain prescription drug benefit information to HHS. The reference to rebates, discounts, and price concessions in section 1150A(b)(2) of the Act excludes bona fide service fees paid to PBMs by drug manufacturers or issuers. Under section 1150A of the Act, bona fide service fees are fees negotiated by PBMs that include but are not limited to “distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).” Section 156.295, implementing section 1150A of the Act, defines bona fide services fees as “fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.”

In light of the comments that we previously received during the process of amending § 158.140(b)(1)(i), we proposed to further amend the MLR rules to add the definition for

³⁰⁰ See 85 FR at 29240–29241.

³⁰¹ The requirements of section 1150A with respect to QHP issuers are codified at § 156.295. In the proposed rule, we proposed to amend that regulation and to codify the requirements with respect to PBMs at a new 45 CFR part 184.

prescription drug rebates and other price concessions to § 158.103 and to clarify that this term excludes bona fide service fees, consistent with how such fees are described in § 156.295. We proposed that this provision become applicable beginning with the 2022 MLR reporting year (MLR reports filed in 2023), which aligns with the applicability date of the amendment to § 158.140(b)(1)(i) and should provide issuers with adequate time to adjust contracts with entities providing pharmacy benefit management services to provide transparency regarding prescription drug rebates and other price concessions they receive from drug manufacturers. We solicited comment on this proposal.

We received public comments on the proposed amendment of § 158.103 to establish the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes. The following is a summary of the comments we received and our responses.

Comment: All of the commenters generally supported the proposal to define prescription drug rebates and other price concessions that issuers must deduct from incurred claims because they agreed it would provide clarity, consistency, transparency, and accuracy for reporting incurred claims in the MLR calculation. A few commenters expressed concern that excluding bona fide service fees from the definition of prescription drug rebates and other price concessions could facilitate evasion and abuse, and incentivize greater use of service fee-generating activities focused on impeding or denying care. These commenters urged HHS to ensure that amounts that are treated as bona fide service fees are in fact bona fide service fees and that this category is not inappropriately exploited to obscure the true cost of prescription drugs.

Response: We agree that including a definition of prescription drug rebates and other price concessions will promote transparency and higher-quality reporting of incurred claims. We also share commenters' concerns that the regulated entities may restructure their contracts in ways that could circumvent the rules regarding the exclusion of bona fide service fees and

emphasize that we will only permit as an exclusion from prescription drug rebates and other price concessions bona fide service fees that meet the definition at §158.103. We intend to continue monitoring developments in the prescription benefit markets in order to ensure that the MLR rules continue to appropriately reflect the prevailing market practices.

Comment: Several commenters requested that HHS clarify that the definition of prescription drug rebates and other price concessions at § 158.103 excludes prescription drug coupons and similar items that benefit enrollees directly at the point of sale, since these items do not reduce issuers' drug costs and may not be known to issuers.

Response: We agree with the commenters and clarify that it was never our intent to include prescription drug coupons and similar items that benefit enrollees directly at the point of sale in the definition of prescription drug rebates and other price concessions at § 158.103. Accordingly, we are modifying the proposed definition of prescription drug rebates and other price concessions in this final rule to clarify that this term excludes any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee, such that no other entity receives any portion of the coupon payment, remuneration, or price concession.

Comment: Several commenters recommended that HHS exclude from the definition of prescription drug rebates and other price concessions at § 158.103 payments for services related to quality improvement activities (QIA).

Response: We disagree with this recommendation. The purpose of the requirement at §158.140(b)(1)(i)(B) that prescription drug rebates and other price concessions must be subtracted from an issuer's incurred claims for MLR purposes is to accurately capture issuers' true expenditures on enrollees' prescription drugs. Separately, section 158.150 requires reporting of QIA expenditures. Excluding amounts attributable to QIA from the definition of prescription drug rebates and other price concessions that must be subtracted from incurred claims would improperly inflate incurred claims, preventing an accurate accounting of prescription drug costs.

Thus, any portion of prescription drug rebates and other price concessions that represents compensation for QIA services should be reported as QIA for MLR purposes.

Comment: Several commenters recommended that HHS remove the term “direct and indirect remuneration” (DIR) from the definition of prescription drug rebates and other price concessions at §158.103. These commenters stated that this term originated within the Medicare Part D program and would be confusing for issuers and PBMs.

Response: We note that in the preambles to both the 2021 Payment Notice proposed rule and the 2021 Payment Notice final rule, we explained that the prescription drug price concessions that must be subtracted from an issuer’s incurred claims are intended to capture “any time an issuer or an entity that provides pharmacy benefit management services to the issuer receives something of value related to the provision of a covered prescription drug (for example, manufacturer rebate, incentive payment, direct or indirect remuneration, etc.).”³⁰² At that time, we did not receive any comments expressing concern with inclusion of DIR in the term price concessions. In addition, we are not persuaded that the DIR definitions used in the Medicare Part D program are inapplicable or inappropriate in the non-Medicare markets, as it includes the same direct and indirect remuneration that is relevant in the commercial markets, such as PBM-retained rebates, PBM rebate guarantee amounts, PBM penalty payments, dispensing incentive payments, risk-sharing amounts, and remuneration from pharmaceutical manufacturers in the form of rebates, grants, reduced price administrative services, legal settlement amounts, and prompt pay discounts from pharmacies that are not included in the negotiated price. However, in response to comments and in order to avoid any confusion between the Medicare and non-Medicare markets, we are making a technical edit to remove the reference to DIR from the definition of prescription drug rebates and other price concessions at § 158.103. Nonetheless, we note that in the definition of prescription drug rebates and price concessions at § 158.103, we continue to intend to require issuers to treat both direct and indirect items of value related to the

³⁰² 85 FR 7139 and 85 FR 29240.

provision of a covered prescription drug, including compensation collected by an issuer or PBM after the point of sale, as prescription drug rebates and other price concessions that must be subtracted from an issuer's incurred claims. Further, HHS intends to continue to review issues surrounding the MLR definition and treatment of prescription drug rebates and other price concessions, and as more information and data become available, HHS may propose revisions in the future as may be necessary or appropriate to ensure that consumers receive value for their premium dollars pursuant to section 2718 of the PHS Act.

Comment: Several commenters recommended that HHS remove the term “receivable” from the definition of prescription drug rebates and other price concessions at § 158.103.

Response: In response to these comments and to preserve consistency with the language used throughout § 158.140, we are making a technical edit to remove the term “receivable” from the definition of prescription drug rebates and other price concessions at § 158.103. However, we note that, similar to other components of incurred claims, prescription drug rebates and other price concessions attributable to enrollees' drug utilization during the MLR reporting year are not always settled and received by the time issuers submit MLR reports to the Secretary. Consequently, while § 158.140 commonly refers to “payments” and “receipts” as well as amounts “paid” and “received,” the MLR Annual Reporting Form Filing Instructions provide more detailed guidance specifying where these terms include amounts that are payable or receivable. Currently, for MLR purposes, issuers report the prescription drug rebate amounts they expect to receive with respect to the reporting year, and QHP issuers and PBMs similarly report such expected amounts for purposes of the reporting required under section 1150A of the Act. Therefore, we intend to clarify in the MLR Annual Reporting Form Filing Instructions that the prescription drug rebates and other price concessions that issuers must subtract from incurred claims (which for the 2022 and later MLR reporting years will include amounts received and retained by PBMs) include the receivable amounts.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing the definition of prescription drug rebates and price concessions at § 158.103 as proposed, with a modification to clarify that the definition excludes any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee, and technical edits to replace the phrase “direct and indirect remuneration” with “remuneration,” and remove the term “receivable.”

2. Premium Revenue (§ 158.130)

We proposed to clarify the MLR premium reporting requirements under § 158.130 for issuers that choose to offer temporary premium credits during a public health emergency (PHE) declared by the Secretary of HHS (declared PHE) in the 2021 benefit year and beyond, when such credits are permitted by HHS. In the August 4, 2020 guidance, Temporary Policy on 2020 Premium Credits Associated with the COVID-19 PHE, CMS adopted a temporary policy of relaxed enforcement to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage to support continuity of coverage for individuals, families and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE.³⁰³ On September 2, 2020, HHS issued an interim final rule on COVID-19 wherein we set forth MLR data reporting and rebate requirements for issuers offering temporary premium credits for 2020 coverage.³⁰⁴ For the 2021 MLR reporting year³⁰⁵ and beyond, we proposed to adopt these MLR data reporting and rebate requirements for all health insurance issuers in the

³⁰³ “Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency,” August 4, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

³⁰⁴ 85 FR 54820 (Sept. 2, 2020).

³⁰⁵ The MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer. See 45 CFR 158.103. The 2021 MLR reporting year refers to the MLR reports that issuers must submit for the 2021 benefit year by July 31, 2022. See 45 CFR 158.110(b).

individual and small group markets³⁰⁶ who elect to offer temporary premium credits during a declared PHE in situations in which HHS issues guidance announcing its adoption of a similar temporary policy of relaxed enforcement to allow such issuers to offer temporary premium credits during the declared PHE.³⁰⁷

We proposed that for purposes of § 158.130, issuers must account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, consistent with any technical guidance set forth in the applicable year's MLR Annual Reporting Form Instructions,³⁰⁸ when such credits are permitted by HHS. Specifically, as clarified in the interim final rule on COVID-19, we proposed that the amount of temporary premium credits³⁰⁹ will constitute neither collected premium nor due and unpaid premium described in the MLR Annual Reporting Form Instructions for purposes of reporting written premium (which is a component of earned premium). Consequently, issuers that offer temporary premium credits during a declared PHE will report as earned premium for MLR and rebate calculation purposes the actual, reduced premium paid when such credits are permitted by HHS.

We solicited comment on this proposal.

We received public comments on the proposal to require issuers for purposes of § 158.130 to account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, consistent with any

³⁰⁶ While this final rule, the interim final rule on COVID-19, and the August 4, 2020 guidance focus on the individual and small group markets, to remove the barriers in support of issuers offering these premium credits to enrollees impacted by a PHE declared by the Secretary of HHS, we note that issuers in the large group market may also, when consistent with state law, offer temporary premium credits and should similarly report the lower, adjusted amount that accounts for the premium credits for MLR purposes.

³⁰⁷ The Secretary of HHS may, under section 319 of the PHS Act, determine that: (a) a disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

³⁰⁸ Available at https://www.cms.gov/cciiio/Resources/Forms-Reports-and-OtherResources/index#Medical_Loss_Ratio.

³⁰⁹ MLR rebates provided in the form of premium credits are different than the temporary premium credits such as those outlined in the August 4, 2020 guidance issued by CMS. When MLR rebates are provided in the form of premium credits, issuers must continue to report the full amount of earned premium and may not reduce it by the amount of MLR rebates provided in form of premium credits, as required by § 158.130(b)(3).

technical guidance set forth in the applicable year's MLR Annual Reporting Form Instructions, when such credits are permitted by HHS. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to adopt the MLR data reporting and rebate requirements for issuers who elect to offer temporary premium credits during a declared PHE in future MLR reporting years. Specifically, these commenters noted that the proposal ensures accuracy and consistency in the MLR reporting and rebate calculation process.

Response: We agree that this proposal provides accuracy and consistency in MLR reporting and rebate calculations and appreciate the comments.

Comment: A few commenters appeared to assume that this proposal sought to permanently codify CMS' temporary policy of relaxed enforcement that allowed issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage to support continuity of coverage for individuals, families and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE and to extend this policy of relaxed enforcement to future years. Some commenters cautioned HHS to ensure that any such premium credits be aligned with state regulations and legislation or be subject to state regulatory approval.

Response: We note that this proposal did not seek to extend CMS' temporary policy of relaxed enforcement or expand issuers' ability to offer temporary premium credits in future years. Rather, we proposed that if HHS were to allow issuers to offer temporary premium credits during a declared PHE in future years, then issuers would account for such temporary premium credits as reductions in earned premium for the applicable MLR reporting years. We continue to be cognizant that state regulators may have additional considerations with respect to any temporary premium credits provided by issuers, and note that both the interim final rule on COVID-19 and the August 4, 2020 guidance required issuers to receive the applicable insurance regulator's permission in advance of providing temporary premium credits for 2020 coverage.

After consideration of all of the comments received and for the reasons stated in our responses, we are finalizing as proposed the clarification that issuers must account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, when such credits are permitted by HHS.

3. Formula for calculating an issuer's medical loss ratio (§ 158.221)

As noted in section IV of the preamble, on March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et al. v. Cochran*, No. 18-2364, 2021 WL 825973 (D. Md. Mar. 4, 2021), vacating 45 CFR 158.221(b)(8), which provided that beginning with the 2017 MLR reporting year, an issuer had the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. Pursuant to this provision, issuers who chose this method of reporting were required to apply it for a minimum of 3 consecutive MLR reporting years and for all of their individual, small group, and large group markets; and all affiliated issuers were required to choose the same reporting method. As a result of the Court's decision, we are finalizing the deletion of § 158.221(b)(8).³¹⁰

With the deletion of § 158.221(b)(8), our regulations will no longer provide issuers the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuers' actual expenditures for activities that improve health care quality. As discussed in section IV of the preamble and consistent with the court's decision, we are reverting to requiring issuers to itemize QIA expenditures, on a prospective basis, beginning with the 2020 MLR reporting year (MLR reports due by July 31, 2021). However, we are not requiring issuers to incur the burden or expense of revising MLR Annual Reporting Forms from prior years or otherwise updating QIA expenditure amounts reported for prior years. In addition,

³¹⁰ Consistent with the removal of § 158.221(b)(8), existing paragraph (b)(9) is redesignated as paragraph (b)(8).

because MLR calculations are based on a three-year average,³¹¹ there will be a transition period during which these averages will continue to reflect the standardized QIA expenditure amounts for those issuers that reported such amounts in the 2017–2019 MLR reporting years.³¹²

4. Rebating Premium if the Applicable Medical Loss Ratio Standard is Not Met (§ 158.240)

In order to allow enrollees to benefit from the ability to receive estimated rebates earlier and to provide MLR reporting flexibilities to issuers that may owe rebates, we proposed to amend § 158.240 by adding paragraph (g) to explicitly allow issuers to prepay a portion or all of their estimated rebates to enrollees for any MLR reporting year. We also proposed to require that issuers that choose to prepay a portion or all of their estimated rebates do so for all eligible enrollees in a given state and market in a non-discriminatory manner.

In the preamble to the proposed rule, we noted that an issuer that prepays a portion or all of its estimated rebate and subsequently determines that such prepayment is less than the total rebate owed to an enrollee would have to incur the costs of disbursing rebates twice: first to disburse the prepaid rebate amount, and again to disburse the remaining rebate amount by the deadlines set forth in §§ 158.240(e) and 158.241(a)(2). Therefore, in order to reduce the regulatory burden on issuers and incentivize issuers to deliver rebates to enrollees sooner, we proposed to add to the new § 158.240(g) a safe harbor under which an issuer that prepays at least 95 percent of the total rebate owed to enrollees in a given state and market for a given MLR reporting year by the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) may, without penalty or late payment interest under § 158.240(f), defer the payment of any remaining rebate owed to enrollees in that state and market until the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) for the following MLR reporting year. This would enable such an issuer to maintain a single rebate disbursement cycle per year, while ensuring that enrollees continue to receive most of the rebate within the regular timeframe.

³¹¹ See 42 USC 300gg-18(b)(1)(B)(ii) and 45 CFR 158.220(b).

³¹² For example, calculations for the 2020 MLR Reporting Year are based on 2018, 2019 and 2020 data.

To further ensure that enrollees do not regularly receive reduced rebates as a result of prepayments, we also proposed that under this safe harbor, the rebate amount remaining after prepayment would not be treated as *de minimis*, regardless of how small the remaining amount is. That is, the *de minimis* provisions in § 158.243 would continue to apply only if the total rebate (the sum of the prepaid amount and any amount remaining after prepayment) owed to an enrollee for a given MLR reporting year is below the applicable threshold.

We noted that § 158.250 requires issuers to provide a notice of rebates at the time any rebate is provided, which includes both rebate prepayments and payments of rebates remaining after prepayment. We also noted that we intend to modify the ICRs approved under OMB Control Number 0938-1164 to add modified standard notices that can be used by issuers that elect to prepay rebates under the proposed new §158.240(g). In addition, we noted that we intend to revise the MLR Annual Reporting Form Instructions to clarify that an issuer that prepays a portion or all of its estimated rebate and subsequently determines that the amount of such prepayment is more than the total rebate owed to an enrollee for that MLR reporting year and that does not recoup the overpayment from the enrollee, may include the overpayment in its rebate payments reported for purposes of calculating the optional limit on the payable rebates under § 158.240(d). We also noted that we intend to revise the MLR Annual Reporting Form Instructions to clarify how issuers that prepay estimated rebates must report such prepayments.

We proposed that the amendment to create new § 158.240(g) would be applicable beginning with the 2020 MLR reporting year (MLR reports filed in 2021). We solicited comment on this proposal, including the proposed applicability date.

We received public comments on the proposed amendments to § 158.240. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposal, stating that it will benefit consumers, provide flexibility and relief for enrollees in future crises, and help consumers maintain comprehensive health coverage. Some commenters recommended that HHS clarify that

rebate prepayment is only permitted if consistent with state law and provided statewide in a nondiscriminatory manner; one commenter requested that rebate prepayment be subject to state regulatory approval and only with the 95 percent safe harbor guardrail. Several commenters opposed the proposal, expressing concern with the operational and administrative burden for State Exchanges and group health plan rebate recipients, consumers favoring issuers that provide prepayments, and the deferred rebates being less likely to reach consumers.

Response: We appreciate the comments in support of this proposal and generally believe that any potential disadvantages of rebate prepayment are outweighed by the benefit of consumers receiving rebates earlier in the year. While we recognize that issuers' ability to reach the original enrollees to provide them with any deferred rebates may diminish as time passes, we believe that the potential harm to consumers that are unable to receive the residual amount remaining after rebate prepayment is mitigated by the 95 percent safe harbor threshold and outweighed by the benefits associated with enrollees' ability to receive rebates earlier than September 30, when they are generally disbursed. We also note that payment of remaining rebate amounts after prepayment may only be deferred until the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) for the following MLR reporting year. We further believe that issuers do not gain a significant advantage by prepaying rebates other than delivering a benefit to their enrollees, and we expect that issuers will consider whether in the group markets that benefit exceeds any complexities that it may create for group policyholders or any administrative burden or operational challenges for the issuer, their enrollees, or the Exchanges. Because a consumer is unlikely to know whether an issuer intends to prepay MLR rebates in any given year prior to purchasing a policy, and since an issuer that pre-paid rebates in a previous year may decide not to pre-pay them in a future year, we do not believe that consumers will be more likely to purchase a policy or enroll in health insurance coverage from any given issuer based on the issuer's prepayment of MLR rebates. And if consumers are able to take rebate prepayment into account when selecting an issuer, we do not see why they should be prevented

from doing so and selecting an issuer that they believe provides a valuable service. We acknowledge the commenters' concerns regarding the potential interaction of rebate prepayment and state rules or State Exchange operations, and are modifying the proposal to clarify that issuers that choose to prepay a portion or all of their estimated rebates must do so to the extent consistent with state law or other applicable state authority. This would include receiving state approval, if required under state law. Further, we note that the regulatory text does provide that any issuer that chooses to prepay a portion or all of their estimated rebates must provide the prepayment to all of the enrollees in that state and market in a non-discriminatory manner.

Comment: One commenter requested that the safe harbor threshold either be lowered to 85 percent or be based on the estimated MLR falling within 0.5 percent of actual MLR, to make the safe harbor more attainable for issuers that owe small rebate amounts and consequently may estimate rebates more accurately in dollar terms.

Response: We have considered this option but concluded that 95 percent is an appropriate safe harbor threshold. Reducing the threshold would expand the safe harbor for all issuers, rather than only issuers that owe relatively small rebates per enrollee, which would result in overall larger rebate amounts being eligible to be deferred for a year. Further, we trust that issuers will evaluate the relative value of prepaying very small per-enrollee rebate amounts early versus the associated administrative costs and the deferral of a fraction of those small per-enrollee rebates.

Comment: One commenter suggested that enrollees should have the option to choose whether an issuer that chooses to prepay a portion or all of their estimated rebates must pay any remaining rebate amounts in full during the current year or may defer the payment of any remaining rebate amounts until the following year under the proposed new § 158.240(g) safe harbor.

Response: We appreciate the commenter's suggestion, but believe that the burden of collecting and implementing each enrollee's election with respect to rebates remaining after

prepayment would be a significant disincentive for issuers to offer rebate prepayment, and as stated above, we generally believe that any potential disadvantages of rebate prepayment are outweighed by the benefit of consumers receiving rebates earlier in the year.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing the amendments to § 158.240 as proposed, with an additional clarification that issuers that choose to prepay a portion or all of their estimated rebates must do so to the extent consistent with state law or other applicable state authority.

5. Form of Rebate (§ 158.241)

We proposed to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to the date that the rules previously provided.

As discussed in the proposed rule, under § 158.240(e), issuers that choose to provide a rebate via a lump-sum check or lump-sum reimbursement to the account used to pay the premium must issue the rebate no later than September 30 following the end of the MLR reporting year. In contrast, § 158.241(a)(2) previously provided that issuers that elect to provide rebates in the form of a premium credit must apply the rebate to the first month's premium that is due on or after September 30 following the MLR reporting year, and that when the rebate is provided in the form of a premium credit and the total amount of the rebate owed exceeds the premium due in October, any excess rebate amount must be applied to succeeding premium payments until the full amount of the rebate has been credited.

Given the proposed addition of § 158.240(g) discussed in the prior section, the fact that an issuer may wish to provide rebates in the form of a premium credit earlier than October, and the desire to reduce the regulatory burden and enable enrollees to receive the benefit of rebates sooner, we proposed to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to September 30. Specifically, we proposed to amend § 158.241(a)(2) to specify that when provided in the form of premium credits, rebates must be applied to premium that is due no later than October 30 following the MLR reporting year. We proposed that this

amendment would be applicable beginning with the 2020 MLR reporting year (rebates due in 2021). We solicited comment on this proposal, including on the proposed applicability date.

We received public comments on the proposal to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to the date that the rules previously provided. The following is a summary of the comments we received and our responses.

Comment: All of the commenters supported the proposal to allow issuers to provide rebates in the form of a premium credit before (rather than only after) September 30 because it would allow consumers to receive the benefit of rebates sooner. One commenter recommended making the amendment effective beginning with the 2021 MLR reporting year in order to enable issuers to continue relying on the related guidance issued by HHS in 2020.

Response: We agree with the commenters that this amendment will benefit consumers. While we do not believe that the proposed applicability date overlaps with previous guidance regarding the timing of rebates provided in the form of premium credits, as that guidance applied to the 2019 MLR reporting year (rebates paid in 2020),³¹³ we agree that there is a potential for confusion, and therefore we are adding a clarification that this amendment will be applicable beginning with *rebates due* for the 2020 MLR reporting year.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing the amendment to § 158.241 as proposed, with a clarification that the amendment will be applicable beginning with rebates due for the 2020 MLR reporting year.

G. Part 184 – Pharmacy Benefit Manager Standards under the Affordable Care Act

1. Prescription Drug Distribution and Cost Reporting by Pharmacy Benefit Managers (§§ 184.10 and 184.50)

³¹³ “Temporary Period of Relaxed Enforcement for Submitting the 2019 MLR Annual Reporting Form and Issuing MLR Rebates in Response to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency,” June 12, 2020. Available at <https://www.cms.gov/files/document/Issuing-2019-MLR-Rebates-in-Response-to-COVID-19.pdf>.

PBMs are third-party administrators that manage the prescription drug benefit for a contracted entity.³¹⁴ This administration typically involves processing claims, maintaining drug formularies, contracting with pharmacies for reimbursement for drugs dispensed, and negotiating prices with drug manufacturers.³¹⁵

The role of PBMs in the prescription drug landscape, including any impact on the rising cost of prescription drugs, is not well understood.³¹⁶ For example, PBMs generate revenue, in part, by retaining the difference between the amount paid by the health plan for prescription drugs and the amount the PBM reimburses pharmacies, a practice commonly referred to as “spread pricing.” While estimates report the increasing prevalence of spread pricing in private health insurance plans,³¹⁷ detailed data on the practice has generally not been collected by plans or by any state or federal regulatory body.

We proposed to add part 184 to 45 CFR subchapter E to codify in regulation the statutory requirement that PBMs under contract with QHP issuers report the data described at section 1150A(b) of the Act to the Secretary and to each QHP for which the PBM administers the prescription drug benefit.

At proposed § 184.10(a)(1), we explained that new part 184 is based on section 1150A of the Act. At proposed § 184.10(b), we proposed that the scope of new part 184 establishes standards for PBMs that administer prescription drug benefits for health insurance issuers which offer QHPs with respect to the offering of such plans. We also proposed definitions for part 184 at new § 184.20. Except for the definition of pharmacy benefit manager, these proposed

³¹⁴ PBMs contract with a variety of health plans, including, but not limited to, individual and small group health plans, large group and self-insured plans, and Medicare Part D drug plans. In this section, we only reference PBMs that contract with a health insurance company to administer the prescription drug benefit for QHPs.

³¹⁵ “Pharmacy Benefit Managers,” Health Affairs Health Policy Brief, September 14, 2017. Available at <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/>.

³¹⁶ Elizabeth Seeley and Aaron S. Kesselheim. “Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead,” Commonwealth Fund, March 2019. Available at <https://doi.org/10.26099/n60j-0886>.

³¹⁷ See “The Prescription Drug Landscape, Explored.” Available at https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf.

definitions would codify terms already in use in parts 144 and 155 of subchapter B of subtitle A of title 45 of the Code of Federal Regulations.

As part of the ACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a state under section 1311 of the ACA³¹⁸ to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section 1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.³¹⁹

In the 2012 Exchange Final Rule, we codified the requirements of section 1150A of the Act, as it applies to QHPs, at § 156.295.³²⁰ On January 1, 2020³²¹ and on September 11, 2020³²², we published **Federal Register** notices and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act, as referenced earlier. As noted earlier in this preamble, we proposed to revise § 156.295 to state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs, the QHP issuer will report the data required by section 1150A of the Act to HHS.

³¹⁸ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the ACA. *King v. Burwell*, 576 U.S. 988 (2015).

³¹⁹ As noted earlier in this preamble, the purposes are: as the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the ACA.

³²⁰ Section 1150A(a)(1) also authorizes the collection of data from PBMs that manage prescription drug coverage under contract with a Prescription Drug Plan sponsor of a prescription drug plan or a Medicare Advantage organization offering a Medicare Advantage prescription drug plan.

³²¹ 85 FR 4993 through 4994.

³²² 85 FR 56227 through 56229.

We proposed to add § 184.50(a) to state that where a PBM contracts with an issuer of QHPs to administer the prescription drug benefit for their QHPs, the PBM is required to report the data required by section 1150A(b) of the Act to the QHP and to the Secretary, at such times, and in such form and manner, as the Secretary shall specify. While we acknowledge that this section applies to both the QHP issuer and their PBMs to report this data, we proposed to implement section 1150A to require PBMs to report this data directly to the Secretary, and only to require the QHP issuer to report the data only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs, as further discussed in the preamble to § 156.295 in this final rule.

We proposed to add § 184.50(a)(1) through (3) to require these PBMs to report the data described at section 1150A(b) of the Act to the Secretary. The data proposed to be collected, as required by section 1150A, are: the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), that is paid by the health benefits plan or PBM under the contract³²³; the aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs³²⁴) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number

³²³ As stated above in the preamble for § 156.295, section 1150A(b)(1) requires the Secretary to collect data by pharmacy type. However, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is a not standard classification currently captured in industry databases or files. To reduce burden, we are not finalizing collecting data by pharmacy type at this time. We intend to collect this information at a time when the imposition of such a requirement would pose reasonable burden. We seek comment on ways that we may impose the collection of data by pharmacy type in the future without imposing unreasonable burden on the industry.

³²⁴ This definition of bona fide service fees was finalized at § 156.295 in the 2012 Exchange Final Rule at 77 FR 18432. There, we finalized this definition to align with the definition of bona fide service fees finalized in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule. See 77 FR 22072 at 22093.

of prescriptions that were dispensed; and the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies (spread pricing), and mail order pharmacies, and the total number of prescriptions that were dispensed.

At new § 184.50(b) and (c), we also proposed to codify the confidentiality and penalty provisions that appear at § 1150A(c) and (d) to PBMs which administer the prescription drug benefits for QHP issuers.

We sought comment on these proposals.

We received public comments on the proposed updates to prescription drug distribution and cost reporting by pharmacy benefit managers (§§ 184.10 and 184.50). We have consolidated the description of the public comments received in response to this proposal at Part 184 as part of the discussion in the preamble above for § 156.295. Please refer to that section for our responses to those comments received.

After consideration of all the comments received and for the reasons stated in our responses, we are finalizing this policy as proposed.

IV. Implementation of the Decision in *City of Columbus, et al. v. Cochran*

On March 4, 2021, the United States District Court for the District of Maryland decided *City of Columbus, et al. v. Cochran*, No. 18-2364, 2021 WL 825973 (D. Md. Mar. 4, 2021). The court reviewed nine separate policies we had promulgated in the “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019” (83 FR 16930) published in the **Federal Register** on April 17, 2018 (the 2019 Payment Notice). The court upheld five of the challenged policies but vacated four others. Specifically, the court vacated the following portions of the 2019 Payment Notice:

1. The 2019 Payment Notice’s extension of the elimination of federal reviews of network adequacy of qualified health plans offered through the FFEs in certain circumstances

by incorporating the results of the states' reviews, first finalized in rulemaking in the Market Stabilization final rule³²⁵ (83 FR 17024 through 17026).

2. The 2019 Payment Notice's cessation of the practice of designating some plans in the FFEs as "standardized options" in an effort to encourage innovation in the individual market (83 FR 16974 through 16975).

3. The 2019 Payment Notice's modification of Exchange income verification requirements for resolving data matching issues related to eligibility for advance payments of premium tax credits to require an individual who attests to a household income within 100 percent to 400 percent of the federal poverty level (FPL), but whose income according to trusted electronic data sources is below 100 percent FPL, to submit additional documentation supporting the attested to household income (83 FR 16985 through 16987).

4. The 2019 Payment Notice's amendment of medical loss ratio requirements to allow issuers to submit either a detailed, itemized report of quality improvement activity (QIA) expenditures or to report a single, fixed QIA amount (83 FR 17032 through 17036).

We intend to implement the court's decision as soon as possible. However, we will not be able to fully implement those aspects of the court's decision regarding network adequacy review and standardized options in time for issuers to design plans and for Exchanges to be prepared to certify such plans as QHPs for the 2022 plan year, and therefore, intend instead to address these issues in time for plan design and certification for plan year 2023. Specifically, in order to implement the court's ruling on the network adequacy provision, HHS will need to set up a new network adequacy review process, and issuers will need sufficient time before the applicable plan year to assess that their networks meet the new regulatory standard, submit network information, and have the information reviewed by applicable regulatory authorities in order for their plans to be certified as QHPs. Issuers might also have to contract with other providers in order to meet the standard. This is not feasible for the QHP certification cycle for

³²⁵ 82 FR 18346, 18371-18372 (April 18, 2017).

the 2022 plan year, since the annual QHP certification cycle generally begins in late April of each year. CMS' planning for the 2022 plan year had already taken into account the provisions that the court vacated before the court issued its decision, and it is too late now to revisit those factors if the process is to go forward in time for plans to be certified by open enrollment later this year. We plan to propose specific steps to address implementation of this aspect of the court's decision in future rulemaking. At that time, we might also address other aspects of the court's decision, including potentially some provisions that the court upheld.

The same is true for the court's decision regarding standardized options. With the rule removing standardized options vacated, we need to design and propose new standardized options that otherwise meet current market reform requirements, and we must also alter the Federal Exchange eligibility and enrollment platform system build (HealthCare.gov) to provide differential display of such plans. Web-brokers that are direct enrollment partners in FFE and SBE-FP states will also need time to adjust their respective systems to provide differential display of such plans on their non-Exchange websites.³²⁶ We will need to design, propose and finalize such plans in time for issuers to design their own standardized options in accord with HHS's parameters and submit those plans for approval by applicable regulatory authorities and for certification by Exchanges as qualified health plans. Again, this is not feasible for the QHP certification cycle for the 2022 plan year, since the annual QHP certification cycle generally begins in late April of each year. CMS' planning for the 2022 plan year had already taken into account the provisions that the court vacated before the court issued its decision, and it is too late now to revisit those factors if the process is to go forward in time for plans to be developed, reviewed and certified by open enrollment later this year.

Although standardized options have been required in the past, we will not be able to simply reinstate the same standardized option plans that previously existed. Specifically, in the last iteration of standardized options we finalized in the 2018 Payment Notice, we created three

³²⁶ See 45 CFR 155.220(c)(3)(i)(H).

sets of standardized options based on FFE and SBE-FP enrollment data and state cost-sharing laws. The basis on which we created these three sets of options as well as a number of other factors in the individual market) have changed considerably since the last iteration of standardized options in 2018. Several such changes include modifications in the most popular plans' cost-sharing structures, shifting enrollment trends, the introduction of new state cost sharing laws that affect standardized option plan designs, and states with FFEs or SBE-FPs transitioning to SBEs (which affects the number of sets of options). As a result of these changes, the sets of standardized options and the design of the options themselves must be adjusted accordingly. Further, we do not have sufficient time prior to the 2022 plan year to conduct a full analysis of the changes that have occurred in the last several years in order to design and propose adequate standardized options suitable for the current environment. Additionally, in prior years, we proposed and finalized standardized option plan designs prior to the start of the QHP certification cycle for the following plan year such that issuers had sufficient time to assess these standardized options in order to determine if they wanted to offer them and take the steps necessary to do so. Even if we were able to design standardized option plans prior to the 2022 plan year, issuers would not have a sufficient amount of time to meaningfully assess any standardized options we might propose and decide whether or not to offer them.

For these reasons, we intend to resume the designation of standardized options and propose specific designs in more complete detail in the 2023 Payment Notice. As such, we will seek comment during the corresponding comment period. In the interim, we encourage states with FFEs or SBE-FPs and unique cost-sharing laws that could affect standardized plan design to contact us to discuss their circumstances.

We can take more immediate steps to begin to implement the court's holdings regarding income verification and QIA reporting. First, as discussed more fully later in this section, we are exercising flexibilities under the Administrative Procedure Act (APA) to rescind or replace

in this final rule relevant parts of the income verification and MLR regulations the court invalidated. Second, we plan to implement accompanying operational policies to begin implementation of the court's order with respect to the impacted income verification regulation.

Specific to income verification, we are deleting the invalidated provision requiring certain consumers to provide information for income verification purposes. We note that HHS's systems automatically generate requests for income verification information for those with income data matching issues, and it will take some time for us to redesign this function. Until that redesign is complete, however, HHS will be able to identify consumers who receive requests for verification information and we have established a manual process to notify those recipients that they need not provide the requested information.

As to QIA reporting, we are deleting the invalidated provision to remove the option to report the fixed standardized amount of QIA. The regulation will thus revert to requiring issuers to itemize QIA expenditures on a prospective basis beginning with the 2020 MLR reporting year (MLR reports due by July 31, 2021).³²⁷ However, we are not requiring issuers to incur the burden or expense of revising MLR Annual Reporting Forms from prior years or otherwise updating QIA expenditure amounts reported for prior years. In addition, because MLR calculations are based on a 3-year average,³²⁸ there will be a transition period during which these averages will continue to reflect in part the standardized QIA expenditure amounts for those issuers that reported such amounts in the 2017–2019 MLR reporting years.³²⁹

V. 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 the Office of Management and Budget (OMB) for review and

³²⁷ With the removal of § 158.221(b)(8), CMS regulations require issuers to separately track and itemize QIA expenditures. See 45 CFR 158.150, 158.151 and 158.221.

³²⁸ See 42 USC 300gg-18(b)(1)(B)(ii) and 45 CFR 158.220(b).

³²⁹ For example, calculations for the 2020 MLR Reporting Year are based on 2018, 2019 and 2020 data.

approval. This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 12. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the 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 ICRs.

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.³³⁰ Table 11 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 11: Adjusted Hourly Wages Used in Burden Estimates

³³⁰ See May 2019 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/2019/may/oes_nat.htm#00-0000.

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr.)	Fringe Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
Compliance Officer	13-1041	\$35.03	\$35.03	\$70.06
Pharmacy Technician	29-2052	\$16.95	\$16.95	\$33.90
Secretaries and Administrative Assistants	43-6014	\$18.84	\$18.84	\$37.68
Billing and Posting Clerks	43-3021	\$19.53	\$19.53	\$39.06
Chief Executives	11-1011	\$93.20	\$93.20	\$186.40
Business Operations Specialist	13-1198	\$38.57	\$38.57	\$77.14
Computer System Analyst	15-1121	\$46.23	\$46.23	\$92.46
Computer Programmer	15-1251	\$44.53	\$44.53	\$89.06
Computer and Information Systems Manager	11-3021	\$75.19	\$75.19	\$150.38
General and Operations Manager	11-1021	\$59.15	\$59.15	\$118.30
Auditor	13-2011	\$38.23	\$38.23	\$76.46
All Occupations	00-0000	\$25.72	\$25.72	\$51.44

B. ICRs Regarding Submission of Adjusted Premium Amounts for Risk Adjustment

45 CFR 153.610 and 153.710 provide that issuers of a risk adjustment covered plan must provide HHS with access to risk adjustment data through a dedicated distributed data environment (EDGE server), in a manner and timeframe specified by HHS. We clarify that, for purposes of risk adjustment data submissions in the 2021 benefit year and beyond when a declared PHE is in effect and HHS permits temporary premium credits, issuers that choose to provide temporary premium credits must submit the adjusted (that is, lower) plan premiums for those months, instead of the unadjusted plan premiums. HHS is finalizing the proposal to require issuers to submit adjusted plan premiums to their EDGE servers for all enrollees whom the issuer has actually provided temporary premium credits as a reduction to the corresponding benefit year premiums. We do not believe that issuers who elect to provide these temporary premium credits during a declared PHE will incur additional operational burden associated with EDGE server data submissions as a result of these requirements because we expect issuers' premium reporting systems will already be configured to enable issuers to upload the billable premiums actually charged to enrollees for the applicable benefit year to the EDGE server. Additionally, the current EDGE server operational guidance for the risk adjustment program allows issuers to submit billable premium changes so there will be no changes to the data submission rules. The burden related to this information collection is currently approved under OMB control number 0938-

1155 (Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals). The information collection request expires on February 23, 2021.

C. ICRs Regarding Direct Enrollment (§§ 155.220 and 155.221)

At § 155.220(c)(6), we are finalizing the proposal that a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission of a number of artifacts of documentation or completion of certain testing processes. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that it will take up to 2 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit the required operational data and web-broker agreement to HHS each year. We estimate that it will take up to 17 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit the required security and privacy assessment documentation to HHS. The total burden for each web-broker would be approximately 19 hours, with an equivalent cost of approximately \$1,466. Based on current web-broker participation and potential market size, we estimate that 30 web-brokers will participate. We estimate that these data collections will have an annual burden of 570 hours with a cost of approximately \$43,970.

We are finalizing the proposal to add additional detail to the operational readiness requirement in § 155.221(b)(4) for direct enrollment entities. In § 155.221(b)(4), we require that a direct enrollment entity must demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection, which may include submission of a number

of artifacts of documentation or completion of various testing or training processes. The required documentation may include business audit documentation including: notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; vulnerability scan results; and an agreement between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that for each direct enrollment entity it will take up to 9 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit a typical documentation package and related information to HHS each year. Based on current EDE participation and potential market size, we estimate that 77 EDE entities will participate in a manner such that they will be required to submit this type of information, and therefore, this data collection will have an annual burden of 693 hours with an annual cost of approximately \$53,458.

In addition, we estimate that it will take up to 72 hours for an Auditor (at an hourly cost of \$76.46) to complete and submit a business requirements audit package for a direct enrollment entity, including audit report and testing results, to HHS. Based on current EDE participation and potential market size, we estimate that 4 EDE entities will participate, and therefore this data collection would have an annual burden of 288 hours with a cost of approximately \$22,020.

We also estimate that it will take up to 122 hours for an Auditor (at an hourly cost of \$76.46) to complete and submit a security and privacy audit package for a direct enrollment entity to HHS each year. Based on current EDE participation and potential market size, we estimate that 14 EDE entities will participate, and therefore this data collection will have an annual burden of 1,708 hours with a cost of approximately \$130,594.

We are finalizing these burden estimates as proposed.

D. ICRs Regarding Income Inconsistencies (§155.320(c))

We anticipate that removing the income verification requirements for resolving data matching issues will reduce burden on those consumers who are identified and notified as having this income inconsistency, saving them approximately 45 minutes since they will not be required to complete associated questions in the application or submit supporting documentation. Based on historical data from the FFE, HHS estimates that approximately 295,000 inconsistencies are generated at the household level. Therefore, eliminating these inconsistencies will reduce burden by approximately 221,250 hours. Using the average hourly wage for all occupations (at an hourly cost \$51.44 per hour), we estimate that the annual reduction in cost for each consumer will be approximately \$39, and the annual cost reduction for all consumers who would have generated this income inconsistency will be approximately \$11,381,100.

The burden related to this information collection is approved under OMB control number 0938-1191 (Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Insurance Marketplaces, Medicaid and Children's Health Insurance Program Agencies), which will be revised to account for this reduced burden. The approval for this information collection expires on September 30, 2022.

E. ICRs Regarding Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

We are finalizing the proposal to revise § 156.295 and add § 184.50 to require QHP issuers or PBMs that contract with QHP issuers to report the data envisioned by section 1150A. We have not previously collected this data; therefore, the burden associated with these proposals will reflect the imposition of the burden for a new collection, and not merely the burden created by changes to existing regulatory text. On January 1, 2020³³¹ and on September 11, 2020,³³² we

³³¹ 85 FR 4993 through 4994.

³³² 85 FR 56227 through 56229.

published notices in the **Federal Register** and solicited public comment on the burden related to these ICRs. Here, we replicated the discussion regarding burden from the information collection published in September 2020 and solicited a third round of public comment on the burden associated with this collection.

The burden associated with this collection is attributed to QHP issuers and PBMs, and the burden estimates were developed based on our previous experience with QHP information reporting activities. We stated that we were unaware of any QHP issuer that does not contract with a PBM to administer their prescription drug benefit. While we invited comment on whether any QHP issuer does not use a PBM, we did not estimate any burden for a QHP issuer to submit data directly. The following burden estimate reflects our expectation that all data will be submitted by PBMs.

Across all 50 states and the District of Columbia, we estimate approximately 40 PBMs will be subject to the reporting requirement. We further estimate that these PBMs, taken as a whole, annually contract with approximately 275 QHP issuers to administer the prescription drug benefit for their QHPs. We estimate that the 275 QHP issuers offer 7,000 total QHPs annually or 25.4 QHPs per QHP issuer. Thus, we estimate that each of the 40 PBMs will report data for 175 QHPs on average each year. We understand that some of these PBMs will contract with more QHP issuers than others, and as such, the reporting requirement will vary per PBM.

Each PBM that administers pharmacy benefits for a QHP issuer will be required to complete a web form and a data collection instrument. The web form will collect data aggregated at the QHP issuer level for all plans and products offered by the QHP issuer combined. The web form will also require the reporting of an allocation methodology that is selected by the PBM to allocate data, where necessary. We expect submitters to maintain internal documentation of the allocation methodologies chosen, as we may need to follow-up with the submitter to better understand the methodology.

PBMs will prepare and submit one data collection instrument per QHP issuer by Health Insurance Oversight System (HIOS) ID. Each data collection instrument will contain information regarding each plan the issuer offers. We estimated that an average PBM will report information for 5,200 NDCs for each QHP. The reports must include the data for all of the plans that the QHP issuer offered in their QHPs in the applicable plan year, even if they have no data to report for that plan year.

Each submitter will also be required to complete an attestation which confirms the data submitted is accurate, complete, and truthful.

We estimate that 40 PBMs will submit data for this reporting requirement, each submitting data for 175 QHPs on average. For each PBM, we estimate that it will take compliance officers approximately 570 hours (for an annual cost of approximately \$39,934 at a rate of \$70.06 per hour), pharmacy technician 350 hours (for an annual cost of \$11,865 at a rate of \$33.90 per hour), secretaries and administrative assistants 175 hours (for an annual cost of \$6,594 at a rate of \$37.68 per hour), and billing and posting clerks 175 hours (for an annual cost of approximately \$6,836 at a rate of \$39.06 per hour) to prepare and submit the information and 8 hours for a chief executive (for an annual cost of approximately \$1,491.20 at a rate of \$186.40 per hour) to review the information and complete the attestation. In total, we estimate it will take a PBM approximately 1,278 hours to respond to this reporting requirement each year on average, for a total annual cost of approximately \$66,719 per PBM to report data. This estimate will vary by PBM, since each PBM will report for a different number of plans, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 40 PBMs combined to be approximately 51,120 hours or \$2,668,796.

We estimate that PBMs will incur burden to complete a one-time technical build to implement the changes necessary for this collection, which will involve activities such as planning, assessment, budgeting, contracting, and reconfiguring systems to generate data extracts that conform to this collection's requirements. We expect that this one-time burden will be

incurred primarily in 2021. We estimate that, for each PBM, on average, it will take project management specialists and business operations specialists 500 hours (at \$77.51 per hour), computer system analysts 1,300 hours (at \$92.46 per hour), computer programmers 2,080 hours (at \$89.06 per hour), computer and information systems managers 40 hours (at \$150.38 per hour) and general and operations managers 50 hours (at \$118.30 per hour) to complete this task. The total one-time burden for a PBM would be approximately 3,970 hours on average, with an equivalent cost of approximately \$356,128. For all 40 PBMs, the total one-time burden will be 158,800 hours for a total cost of approximately \$14.2 million. For all 40 PBMs, the average annual burden in 2021-2023 incurred for implementation and reporting will be approximately 87,000 hours with an average annual cost of approximately \$6.5 million.

We estimate that 275 QHP issuers will need to identify for the PBMs each year which plans are QHPs. For each QHP issuer, we estimate that it will take secretaries and administrative assistants 7 hours (for an annual burden of \$263.76 at a rate of \$37.68 per hour) to identify, on average, approximately 25 QHPs offered by a QHP issuer. This estimate will vary by QHP issuer, since each QHP issuer would identify a different number of QHPs, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 275 QHP issuers combined to be 1,925 hours or approximately \$72,534.

Comment: We received one comment that inquired whether QHPs that are part of integrated systems comprised of health plans that operate their own pharmacy network are subject to this reporting requirement, and if so, whether such a system would qualify as a PBM or QHP issuer under this burden estimate.

Response: While there is nothing in the statute that would allow exemption from this reporting requirement based on the business structure of reporting entities, we acknowledge that some entities may have initial difficulty complying with the instructions and reporting mechanisms described in the ICR. We intend to provide robust technical assistance to all

reporting entities to minimize the upfront burden created by this collection. For purposes of this estimate, we consider such a system a PBM that will report this data.

We are finalizing as proposed.

F. ICRs Regarding Medical Loss Ratio (§§ 158.103, 158.130, 158.240, 158.241)

We are finalizing our proposal to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes under § 158.140(b)(1)(i). We are also finalizing the proposal to add a new § 158.240(g) to explicitly allow issuers to prepay a portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, we are finalizing the proposal to amend § 158.241(a)(2) to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Finally, are finalizing the proposal to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS. We anticipate that implementing these provisions will require minor changes to the MLR Annual Reporting Form, but will not significantly increase the associated burden. The burden related to this information collection was approved under OMB control number 0938-1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS-10418)). The control number expired on October 31, 2020. A revised collection of information seeking OMB approval for an additional 3 years is currently under review by OMB.

G. Summary of Annual Burden Estimates for Requirements

TABLE 12: Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB control number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$)	Total Cost (\$)
§ 155.220(c)(6)	0938-NEW	30	30	19	570	\$43,970	\$43,970
§ 155.221(b)(4)	0938-NEW	77	77	9	693	\$53,458	\$53,458
§ 155.221(b)(4) - Business Requirements Audit	0938-NEW	4	4	72	288	\$22,020	\$22,020
§ 155.221(b)(4) - Security and Privacy Audit	0938-NEW	14	14	122	1,708	\$130,594	\$130,594
156.295 & 184.50 (PBM Burden)	0938-NEW	40	40	2,175	87,000	\$6,527,571	\$6,527,571
156.295 & 184.50 (QHP Issuer Burden)	0938-NEW	275	275	7	1,925	\$72,534	\$72,534
Total		440	440		92,184	\$6,850,147	\$6,850,147

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 12.

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 requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule (CMS-9914-F2), please visit the CMS Web site at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410–786–1326.

VI. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended, in response to public comments and take effect, in accordance with the APA (Pub. L. 79-404), 5 U.S.C. 553 and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of proposed rulemaking in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and

issues involved. Section 553(c) of the APA further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Section 553(b)(B) of the APA authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 553(d) of the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Finally, the Congressional Review Act (CRA) (Pub. L. 104-121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines 5 U.S.C. 801(a)(3) and 808(2).

In *City of Columbus*, as explained earlier in the preamble, the district court vacated four provisions of the 2019 Payment Notice. Implementing the court's order as to two of those provisions, regarding income verification and QIA expenditure reporting, can be accomplished immediately. We find that it is necessary and in the public interest to implement these two provisions quickly to provide immediate notice to the regulated community on what standards will apply and to prevent injury to the public. A delay in implementing the court's decision regarding these two provisions would cause unnecessary harm. HHS needs to move quickly on these two provisions to fill the regulatory void caused by the court's vacatur. Without immediate action, there will be confusion among issuers and consumers regarding what is expected, which we find to be contrary to the public interest. We find it impractical to wait months to clarify what standards apply after the vacatur of the two policies. In this rule we have explained the impact of the court's decision.

With regard to MLR QIA expenditures, we need to clarify that CMS will implement the court's decision going forward, that is, as CMS explained above, issuers will have to report actual data and cannot report standardized QIA expenditure amounts for 2020 and future MLR reporting years, but issuers will not be required to go back and correct their MLR Annual Reporting Forms for 2017-2019. We find it necessary to immediately clarify issuer reporting obligations to avoid issuer confusion regarding how to report QIA on the 2020 MLR Annual Reporting Forms (due by July 31, 2021) and to mitigate the potential of any delay or inaccuracy in providing consumers rebates that may be owed for the 2020 MLR reporting year. In vacating the QIA provision of the 2019 Payment Notice, the court found that the statute requires the itemization of QIA expenditures and does not permit a reporting of such expenses as a standard percentage of earned premium. In light of the court's decision, additional public comments could not meaningfully impact whether CMS is authorized to allow the standardized reporting of QIA expenses. For this additional reason, we find good cause to dispense with any delay in implementing the court's decision on this issue to allow for a comment period, because such a delay would be unnecessary.

With regard to income verification requirements, in which the court vacated the requirement imposed on consumers to provide verification if certain sources of information indicated a variance from a consumer's reported income, we find it necessary and in the public interest to immediately suspend enforcement of these provisions to ensure that consumers are not improperly denied advance payments of premium tax credits. Any delay in clarifying what is required after the court's decision will create confusion and interfere with consumers' access to health coverage. We have concerns that any delay in implementing clarification of this rule could lead eligible consumers to improperly losing coverage if they are unable to produce documentation compliant with the income verification requirements. Without immediate changes, the public, and particularly consumers who are eligible for advance payments of the

premium tax credits, may be deterred in accessing advance payments of the premium tax credits that allow them to afford coverage.

For these reasons, we find it necessary and in the public interest to move quickly and without the delay that would accompany a period for notice and comment to address the court's decision regarding the QIA provisions and income verification requirements. We find good cause for waiving notice-and-comment rulemaking and the delay in effective date given the decision of the district court and the public interest in expeditious implementation of the district court's ruling. Immediately taking the steps described in section IV. of this final rule to implement the court's decision regarding income verification and QIA reporting, including removing the regulation text at §§ 155.320(c) and 158.221(b)(8) directly in this final rule rather than through the normal notice-and-comment rulemaking cycle and waiving delay of the effective date, will ensure an expeditious implementation of those aspects of the court's decision and remove any doubt about what standards apply after that decision. We believe rulemaking without notice and comment for these limited purposes is a reasonable response to the court's order that will minimize confusion over the current status of our rules in those two areas. Therefore, we find good cause to waive notice-and-comment rulemaking for the provisions in section IV. of this final rule, waive delay of the effective date, and to issue these changes as part of this final rule.

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule includes standards related to the risk adjustment program and cost sharing parameters for the 2022 benefit year and beyond. It also includes changes related to special enrollment periods; direct enrollment entities; the administrative appeals process with respect to health insurance issuers and non-federal governmental group health plans; and the medical loss ratio program. In addition, it includes changes to the regulation to require the reporting of certain prescription drug information for QHPs or their PBM.

B. Overall Impact

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any one 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 one 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. An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and a “significant” regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of \$100 million or more in at least

one year, and therefore, meets the definition of “significant rule” under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

The provisions in this final rule aim to ensure that consumers continue to have access to affordable coverage and health care, and that states have flexibility and control over their insurance markets. They will reduce regulatory burden, reduce administrative costs for states, ensure greater market stability, increase transparency and availability of QHP survey data, and increase transparency on the impact of PBMs on the cost of prescription drugs for QHPs. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage.

Affected entities, such as Exchanges, issuers and FFE Classic DE and EDE partners, will incur costs to implement new special enrollment period requirements. Issuers will incur costs to comply with audits and compliance reviews of risk adjustment covered plans, reinsurance-eligible plans, and APTC, CSRs, and user fees requirements. Web-brokers and direct enrollment entities will incur costs to comply with operational readiness demonstration requirements. QHP issuers and PBMs will incur costs to implement and operationalize drug data reporting. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

Comment: A few commenters stated that the RIA in the proposed rule was inadequate.

Response: As explained in the proposed rule, we are unable to quantify all the effects of the provisions of this rule. Therefore, we have included qualitative discussions of costs and benefits related to the provisions in this final rule.

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

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

This final rule implements standards for programs that will have numerous effects, including allowing consumers to have continued access to coverage and health care, 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 13 reflect non-quantified impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers.

We are finalizing the risk adjustment user fee of \$0.25 PMPM for the 2022 benefit year to operate the risk adjustment program on behalf of states,³³³ which we estimate to cost approximately \$60 million in benefit year 2022. We expect risk adjustment user fee transfers from issuers to the federal government to remain steady at \$60 million, the same as those estimated for the 2021 benefit year.

³³³ As noted earlier in this rule, no state has elected to operate the risk adjustment program for the 2022 benefit year; therefore, HHS will operate the program for all 50 states and the District of Columbia.

TABLE 13: Accounting Statement

Benefits:				
Qualitative:				
<ul style="list-style-type: none"> Continued access to coverage and health care due to new special enrollment periods, and due to change in measure of premium growth to calculate the premium adjustment percentage index. Increased probability that consumers are able to maintain continuous coverage as a result of receiving MLR rebates sooner. Increased transparency on the impact of PBMs on the cost of prescription drugs for QHPs. 				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	- \$ 31.57 million	2020	7 percent	2021-2025
	- \$ 30.99 million	2020	3 percent	2021-2025
Quantitative:				
<ul style="list-style-type: none"> Costs incurred by web-brokers and direct enrollment entities to comply with requirements related to demonstration of operational readiness and compliance with applicable requirements. Costs incurred by issuers and PBMs to implement and operationalize drug data reporting, estimated to be approximately \$14.2 million in 2021 and approximately \$2.7 million in 2022 onwards. Reduction in costs to consumers, since certain consumers will no longer be required to provide information for income verification purposes, estimated to be approximately \$11.38 million annually starting in 2021. Costs incurred by State Exchanges to complete the necessary system changes to remove functionality for processing data matching issues, estimated to be approximately \$3.15 million in 2021. Reduction in operational costs to FFEs and State Exchanges due to the rescission of the requirement to process data matching issues, estimated to be approximately \$4.57 million annually starting in 2021. Costs incurred by issuers for audits and compliance reviews of risk adjustment covered plans, audits and compliance reviews of reinsurance-eligible plans, and audits and compliance reviews of APTC, CSR, and user fee programs, estimated to be approximately \$2.1 million on average annually in 2021-2025. Reduction in potential costs to Exchanges since they would not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be savings of \$113 million in 2022. Regulatory familiarization costs of approximately \$83,000 in 2021. 				
Qualitative:				
<ul style="list-style-type: none"> Increased costs due to increases in providing medical services (if health insurance enrollment increases). 				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Federal Annualized Monetized (\$/year)	\$266.1 million	2020	7 percent	2021-2025
	\$277.3 million	2020	3 percent	2021-2025
Other Annualized Monetized (\$/year)	\$23 million	2020	7 percent	2021-2025
	\$23 million	2020	3 percent	2021-2025
Quantitative:				
<ul style="list-style-type: none"> Federal Transfers: Increase in premium tax credit payments estimated to be approximately \$460 million in 2023, \$480 million in 2024, and \$490 million in 2025, due to the change in measure of premium growth to calculate the premium adjustment percentage index. Other Transfers: Increase in rebate payments from issuers to consumers due to the removal of the option to report a single QIA activity expense amount equal to 0.8 percent of earned premium, estimated to be \$23 million annually beginning with the 2020 MLR reporting year (rebates payable in 2021). 				

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the ACA's impact on federal spending, revenue collection, and insurance enrollment. The ACA ends the transitional reinsurance program and temporary risk corridors program after the benefit year 2016. Therefore, the costs

associated with those programs are not included in Table 13 or 14. Table 14 summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2022 through 2026, with the additional, societal effects of this final rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO’s estimates of the budget impact of the premium stabilization programs that are described in Table 14.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions in this rule are consistent with our previous estimates in the 2021 Payment Notice for the impacts associated with the APTC and the premium stabilization programs.

TABLE 14: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2022-2026, in billions of dollars³³⁴

Year	2022	2023	2024	2025	2026	2022-2026
Risk Adjustment and Reinsurance Program Payments	6	6	7	7	8	34
Risk Adjustment and Reinsurance Program Collections	6	6	7	7	8	34

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.

Source: Congressional Budget Office. *Net Federal Subsidies Associated With Health Insurance Coverage, 2020 to 2030*. March 6, 2020. Available at <https://www.cbo.gov/system/files/2020-03/51298-2020-03-healthinsurance.pdf>.

1. Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets (§ 147.104)

The revision to § 147.104(b)(4)(ii) will allow an individual or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to use the date the individual knew, or reasonably should have known, of the occurrence of the triggering event as the date of the triggering event for a special enrollment period to enroll in individual market coverage through or outside of an Exchange. This will enable consumers to maintain continued access to coverage and health care.

³³⁴ Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments to Treasury under section 1341(b)(3)(B)(iv) of the ACA and to CMS for administrative expenses under section 1341(b)(3)(B)(ii) of the ACA, refunds, and allowable activities.

2. CMS Enforcement in Group and Individual Markets (Part 150) and Administrative Review of QHP Issuer Sanctions (Part 156, Subpart J)

We are removing the requirement to file submissions to the Departmental Appeals Board in triplicate and instead require electronic filing. Based on our experience, such filings are infrequent, and this proposed change will not have a significant impact. An entity filing a submission will experience a small reduction in costs related to printing and mailing the submission.

3. Risk Adjustment (Part 153)

The risk adjustment program is a permanent program created by section 1343 of the ACA 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 part 153. If a state is not approved to operate, or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on its behalf. For the 2022 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. For the 2022 benefit year, we used the same methodology that we finalized in the 2020 Payment Notice to estimate our administrative expenses to operate the program. Risk adjustment user fee costs for the 2022 benefit year are expected to remain steady from the prior 2021 benefit year estimates of approximately \$60 million. We estimate that the total cost for HHS to operate the risk adjustment program on behalf of all 50 states and the District of Columbia for 2022 will be approximately \$60 million, and the risk adjustment user fee will be \$0.25 PMPM. Because of the constant costs estimated for the 2022 benefit year, we expect the final risk adjustment user fee for the 2022 benefit year to have

no additional financial impact on issuers of risk adjustment covered plans or the federal government.

Additionally, for the risk adjustment factors, we are finalizing an approach to recalibrate the HHS risk adjustment models for the 2022 benefit year by using the 2016, 2017 and 2018 enrollee-level EDGE data, the same data years used for the 2021 benefit year.³³⁵ We are adopting an approach of using the 3 most recent consecutive years of available enrollee-level EDGE data that are available in time for incorporating the data in the draft recalibrated coefficients published in the proposed rule for recalibration of the risk adjustment models for the 2022 benefit year and beyond. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2021 benefit year to the 2022 benefit year. We are also finalizing the continuation of a pricing adjustment for Hepatitis C drugs for all three models (adult, child and infant). Overall, these changes make limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the risk adjustment program.

We are finalizing the requirement that issuers that choose to offer premium credits to consumers during a declared PHE, when HHS permits such credits, must report the adjusted plan premium amount, taking into account the credits provided to consumers as a reduction to premiums for the applicable months for risk adjustment data submissions for the 2021 benefit year and beyond. We do not believe that the clarifications regarding risk adjustment reporting in this provision will impose additional administrative burden on health insurance issuers beyond the effort already required to submit data to HHS for the purposes of operating risk adjustment, as previously estimated in the interim final rule on COVID-19 (85 FR 54820).

³³⁵ As discussed earlier, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

In the 2021 Payment Notice, HHS finalized the risk adjustment state payment transfer formula under the HHS risk adjustment methodology for the 2021 benefit year, and reaffirmed that HHS will continue to operate the risk adjustment program in a budget neutral manner. As finalized in this rule, we will maintain the same methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking.³³⁶ Therefore, there is no net aggregate financial impact on health insurance issuers or the federal government as a result of the risk adjustment provisions with respect to the finalized proposals regarding the methodology, as well as the premium credit related provisions. However, while risk adjustment transfers are net neutral in aggregate, we recognize that individual issuers may be financially impacted by reduced transfers (either lower risk adjustment payments or lower risk adjustment charges) if any issuer in the issuer's state market risk pool provides premium credits to enrollees in future benefit years during a declared PHE when HHS permits such credits. The extent of this impact will vary based on the number of issuers in a state market risk pool that elect to provide the temporary premium credits during a declared PHE, the amount of these premium credits provided, as well as the market share of the issuers that provide these premium credits.

We do not believe that the impact of this provision will vary from what was previously estimated in the interim final rule on COVID-19 (85 FR 54820). Similar to our analysis of regulatory impacts in the interim final rule on COVID-19, we recognize the potential for financial impacts for individual issuers as a result of these clarifications. We believe that if HHS permitted issuers that provided premium credits when permitted by HHS during a declared PHE to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur which could also financially impact individual issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-than-average risk

³³⁶ As finalized in the 2020 Payment Notice, we intend to also maintain the high-cost risk pool parameters with a threshold of \$1 million and a coinsurance rate of 60 percent for the 2020 benefit year and beyond unless amended through notice with comment rulemaking. See 84 FR at 17480 through 17484.

enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool.

For all of these reasons, we believe that requiring issuers that offer temporary premium credits when permitted by HHS for 2021 and future benefit years' coverage to accurately report to the EDGE server the adjusted, lower premium amounts actually charged to enrollees is most consistent with existing risk adjustment program requirements. We also believe this requirement will mitigate the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts charged to enrollees, while avoiding additional financial burden on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts.

We also are providing more clarity regarding audits and establishing authority to conduct compliance reviews of issuers of risk adjustment covered plans by finalizing amendments to § 153.620(c), with slight modifications to certain audit timeframes in response to comments requesting issuers be provided more time to provide the initial audit data submissions and written corrective action plans. Issuers being audited under the risk adjustment program will be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. We are also codifying our authority to recoup risk adjustment

(including high-cost risk pool) payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with risk adjustment program (including high-cost risk pool) audits will take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$14,356. While the number of issuers participating in the risk adjustment program varies per benefit year, (for example, there were 751 issuers participating in the risk adjustment program for the 2016 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30-60 issuers per benefit year, and intends to focus these audits on payments under the high-cost risk pool.³³⁷ Depending on the number of issuers audited each year, the total cost to issuers being audited will be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

We anticipate that compliance with risk adjustment program (including high-cost risk pool) compliance reviews will take 30 hours by a business operations specialist (at a rate of \$77.14 per hour), 10 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 5 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,589. While the number of issuers participating in the risk adjustment program varies per benefit year, (for example, there were 751 issuers participating in the risk adjustment program for the 2016 benefit year), HHS only intends to conduct compliance reviews for no more than 15 issuers per benefit year and intends to focus these reviews on payments under the high-cost risk pool.³³⁸ The total annual cost to issuers undergoing compliance reviews will be approximately \$53,836.

³³⁷ Currently, HHS uses HHS-RADV to audit the actuarial risk reported by issuers to their EDGE servers that is used for performing calculations under the state payment transfer formula. See 45 CFR 153.350 and 153.630.

³³⁸ Currently, HHS uses HHS-RADV to audit the actuarial risk reported by issuers to their EDGE servers that is used for performing calculations under the state payment transfer formula. See 45 CFR 153.350 and 153.630.

We are increasing the materiality threshold for EDGE discrepancies, beginning in the 2020 benefit year of HHS-operated risk adjustment, so that HHS may only take action if the amount in dispute is equal to or exceeds \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less. As a result of this change, some discrepant issuers will no longer be charged for their EDGE data error. In addition, issuers in the same state market risk pool as the discrepant issuer will not receive positive adjustments to their risk adjustment transfers. This is because HHS's process for addressing material EDGE data discrepancies is to recalculate the dollar value of any difference in risk adjustment transfers, charge the discrepant issuer for the difference, and distribute the amount collected from the discrepant issuer to the issuers in the same state market risk pool who were harmed. Based on analysis of discrepancies from prior years' data, payments to these issuers who were harmed by the discrepant issuer's error are occasionally as low as \$1.00 and typically represent a fraction of one percent of the issuer's overall transfers in the state market risk pool for the applicable benefit year. We anticipate that this change will have a minimal impact on regulatory burden. There might be a slight reduction in administrative burden to some issuers who currently report, and receive adjustments for, EDGE discrepancies that are less than a fraction of total state market risk pool transfers.

4. Audits of Reinsurance-Eligible Plans (§153.410(d))

We are finalizing the amendments to §153.410(d) providing more clarity regarding audits and establishing authority to conduct compliance reviews of reinsurance-eligible plans, with slight modifications to certain audit timeframes in response to comments requesting issuers be provided more time to provide the initial audit data submissions and written corrective action plans. Issuers of reinsurance-eligible plans being audited will be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in

a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. We are also codifying our authority to recoup reinsurance payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with reinsurance program audits will take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$14,356. There were 557 issuers participating in the reinsurance program for the 2015 benefit year and 496 issuers participating in the reinsurance program for the 2016 benefit year; however, HHS will only audit a small percentage of these issuers, roughly 30-60 issuers per benefit year. As noted above, we also intend to combine the 2015 and 2016 benefit year reinsurance audits to reduce the burden on issuers subject to such audits. Depending on the number of issuers audited for each benefit year, the total cost to issuers being audited will be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

We anticipate that compliance with reinsurance program compliance reviews will take 30 hours by a business operations specialist (at a rate of \$77.14 per hour), 10 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 5 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,589. There were 557 issuers participating in the reinsurance program for the 2015 benefit year and 496 issuers participating in the reinsurance program for the 2016 benefit year; however, HHS only intends to conduct compliance reviews for no more than 15 issuers per benefit year and intends to focus these reviews on payments received by reinsurance-eligible plans under the program. The total annual cost to issuers undergoing compliance reviews will be approximately \$53,836.

5. HHS Risk Adjustment Data Validation (§153.630(g))

We are codifying two previously-established exemptions from HHS-RADV under § 153.630(g). These exemptions apply when the issuer only has small group carryover coverage for the applicable benefit year or when an issuer is the sole issuer in the state market risk pool for the applicable benefit year (and did not participate in another risk pool with other issuers for that benefit year). We further note that these new regulatory provisions are not establishing new exemptions; instead, the amendments to §153.630(g) merely codify existing policies and previously established exemptions from HHS-RADV for these subsets of issuers. The impact of the exemption for sole issuers was addressed in the 2019 Payment Notice and the discussion of exempting small group carryover coverage issuers was set forth in the 2020 Payment Notice.³³⁹ Under these exemptions, these issuers are not be required to complete HHS-RADV for the given benefit year, and therefore, they will have a decreased administrative burden. However, given that these exemptions are limited to issuers only offering small group carry-over coverage and issuers who are sole issuers in all markets in a state, we estimate that approximately 13 issuers will be exempt from HHS-RADV for a given benefit year under these exemptions.

We are also changing the HHS-RADV collections timeline from the timeline finalized in the 2020 Payment Notice in response to stakeholder feedback. Under the revised timeline, we will implement the collection of HHS-RADV charges and disbursement of payments in the calendar year in which HHS-RADV results are released. We do not believe this will change the administrative burden previously estimated in the 2020 Payment Notice³⁴⁰ as we understand that the majority of states and issuers follow a timeline that aligns more closely with the one in this rulemaking and few pursued the flexibility provided under the timeline finalized in the 2020 Payment Notice.

6. Direct Enrollment (§§ 155.220 and 155.221)

a. QHP Information Display on Web-broker Websites

³³⁹ 83 FR 17047 and 83 FR 17504.

³⁴⁰ See 84 FR 1507.

After consideration of comments received, we are not finalizing the proposal to provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for QHPs in certain circumstances. As explained above, we intend to further consider these issues and clarify the display requirements for web-broker non-Exchange websites in future rulemaking. Until addressed in future rulemaking, beginning at the start of the open enrollment period for plan year 2022, web-broker non-Exchange websites will be required to display all QHP information received from the Exchange or directly from QHP issuers, consistent with the requirements of § 155.205(b)(1) and (c) for all available QHPs with the exception of medical loss ratio information and transparency of coverage measures under § 155.205(b)(1)(vi) and (vii). This interim approach does not establish new requirements and instead represents a change in the exercise of enforcement discretion regarding the standardized comparative information web-brokers are required to display under existing regulations following our consideration of comments on the proposed changes to the web-broker QHP display requirements.³⁴¹ We previously estimated the administrative burden related to the display of QHP information on web-broker websites in the 2013 Program Integrity final rule.³⁴²

b. Web-broker and Direct Enrollment Entity Operational Readiness Review Requirements

At § 155.220(c)(6), we are finalizing that a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection. As reflected in § 155.220(c)(6)(i) through (iv), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy

³⁴¹ See 45 CFR 155.220(c)(3)(i)(A) and (D).

³⁴² See 78 FR 54128.

assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes may include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers will have to maintain and provide access to testing environments that reflect their prospective or actual production environments. These amendments codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.³⁴³ Some of these requirements, such as the collection of operational data, have effectively existed for many years, and so they will impose little to no new burden. The collection of security and privacy assessment documentation is a new requirement, although historically the web-broker agreement has required web-brokers to attest to the implementation and assessment of privacy and security controls. As a result, web-brokers should have historically completed any technical implementation of the controls and should be familiar with assessment of those controls. Completion of enrollment testing is also a new requirement, but use of the direct enrollment pathways inherently requires a web-broker's platform to be capable of processing enrollments. Therefore, the burden of testing that functionality will be very limited. Website reviews have been conducted historically and are performed by HHS, so there will be no burden to web-brokers associated with the completion of those reviews. The burden related to these requirements is discussed in the Collection of Information Requirements section in this rule.

³⁴³ See, for example, "Updated Web-broker Direct Enrollment Program Participation Minimum Requirements," May 21, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf>.

We are revising § 155.221(b)(4) to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new § 155.220(c)(6), these amendments codify in § 155.221(b)(4) additional details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We note that these requirements are in addition to the operational readiness requirements at new § 155.220(c)(6) for web-brokers, although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in direct enrollment programs and the source and type of documentation.

In paragraph (b)(4), we require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We add new paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit or complete, in the form and manner specified by HHS, a number of artifacts of documentation or various testing or training processes. The documentation may include business audit documentation including: notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results. Submission of agreements between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program may also be required. Required testing may include

eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in direct enrollment programs. We expect minimal new burden associated with this policy as these requirements have historically been established through agreements EDE entities have executed with HHS, and therefore entities have completed these tasks in the past to be able to use the EDE pathway. The burden related to these requirements is discussed in the Collection of Information Requirements section in this final rule.

c. Direct Enrollment Entity Plan Display Requirements

We are revising § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. This change is a revision of a policy adopted in 2019. We anticipate this policy will provide increased flexibility and believe many direct enrollment entity websites are already designed in a manner largely consistent with this proposal, and therefore the burden associated with it is minimal.

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

a. Income Inconsistencies (§155.320(c))

In the 2019 Payment Notice we estimated a one-time burden on Exchanges for necessary system changes to meet the requirement related to data matching issues. The 2019 Payment Notice estimate did not take into account the ongoing operational cost for processing data matching issues from this requirement, because ongoing operational costs are dependent on the Exchange's number of applicants with income inconsistencies and the threshold for setting a data matching issue which was unknown at the time.

Now that we are changing this requirement, we expect a cost saving and burden reduction. We estimate the amendments to § 155.320(c) will create a one-time cost for an Exchange of approximately \$450,000 to complete the necessary system changes to remove functionality for this policy. We estimate that approximately half of the State Exchanges implemented verification functionality in 2019 or 2020. Therefore, for 7 State Exchanges, the estimated total cost will be \$3.15 million.

Based on plan year 2019 and 2020 data of the volume of income inconsistencies generated in the FFEs, we estimate that approximately 295,000 fewer inconsistencies will be generated annually by FFEs by removing this requirement and will result in annual savings of approximately \$3,560,650 for FFEs. We anticipate additional ongoing annual savings for FFEs estimated at \$242,550 due to the reduction of approximately 385,000 mailed consumer notices (approximately \$0.63 per notice). We estimate that approximately 57,361 fewer inconsistencies will be generated annually by State Exchanges by removing this requirement and will result in annual savings of approximately \$692,349 annually for State Exchanges. Likewise, we anticipate additional ongoing annual savings for State Exchanges estimated at \$74,861 due to the reduction of approximately 10,694 mailed consumer notices. Total annual savings for FFEs and State Exchanges is estimated to be approximately \$4,570,410. We note that there could also be additional savings in appeals costs.

b. Employer Sponsored Coverage (155.320(d))

As discussed previously in the preamble, as for benefit years 2020 and 2021, we will not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4) for benefit year 2022. HHS's experience conducting random sampling revealed that employer response rates to HHS's request for information were low. The manual verification process described in paragraph (d)(4)(i) requires significant resources and government funds, and the value of the results ultimately does not appear to outweigh the costs of conducting the work because only a small percentage of sample enrollees have been determined by HHS to have

received APTC/CSRs inappropriately. We estimate the annual costs to conduct sampling on a statistically significant sample size of approximately 1 million cases to be approximately \$6 million to \$8 million for the Exchanges on the Federal platform and State Exchanges that operate their own eligibility and enrollment platforms. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. We estimate that the total annual cost for the Exchanges on the Federal platform and the 15 State Exchanges operating their own eligibility and enrollment platform in 2022 would have been approximately \$113 million. Relieving Exchanges of the requirement to conduct sampling for benefit year 2022 will therefore result in total savings of approximately \$113 million. We sought comment on this estimate.

Comment: While we did not receive specific comments on this estimate, one commenter did note that they supported the proposal but encouraged HHS to consider the costs and benefits of any new evidence-based alternative approach for employer-sponsored coverage verification and to assess whether any benefits would be significant enough to warrant future regulatory action on this issue.

Response: Given HHS's own findings that the manual verification process described in paragraph (d)(4)(i) requires significant resources and government funds to fully operationalize, we agree with the commenter that HHS should consider all costs and benefits of any future proposed verification process that is evidence-based as we do not wish to increase administrative burden on states, employers, consumers, and taxpayers. We will continue to explore the best approach for employer sponsored coverage verification, while taking into consideration the cost and benefits of such an approach in future rulemaking.

8. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for APTC

We are adding a new paragraph at § 155.420(a)(4)(ii)(C) to require Exchanges, no later than January 1, 2024, to allow enrollees and their dependents who qualify for a special

enrollment period because they become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of any metal level. We anticipate that this change will help reduce Exchanges' implementation burden by simplifying the policy and providing additional time to operationalize it, which some Exchanges may need in light of competing priorities such as the need to implement changes to calculate financial assistance established in the American Rescue Plan Act of 2021. We also expect that this policy will help impacted enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of losing a potentially significant amount of financial assistance to help them purchase coverage. For example, an enrollee impacted by an increase to his or her monthly premium payment may change to a bronze-level plan, or to catastrophic coverage if they are otherwise eligible. Relatedly, this proposal may benefit the individual market risk pool by encouraging healthy individuals to maintain continuous coverage. Previously, an enrollee who lost APTC eligibility had only two choices: paying the full premium or terminating his or her coverage. Healthy individuals who lose APTC may be more likely to terminate coverage due to increased premium liability, while enrollees who have one or more medical conditions will be incentivized to maintain coverage in spite of the additional expense. This provision will serve to facilitate continuous coverage of healthy individuals by giving them the ability to enroll in a new plan with a lower premium, thereby supporting a healthier risk pool. Finally, the American Rescue Plan Act of 2021 will prevent some individuals from losing a significant amount of APTC based on a relatively small change in household income, because it allows individuals whose household income exceeds 400 percent FPL to qualify for a premium tax credit if they are otherwise eligible. However, we believe that some consumers will still benefit from this flexibility to plan category limitations, in part because, as described in preamble, there are scenarios other than a household income increase that may cause consumers to become ineligible for APTC.

As discussed in the proposed rule, we did not believe that this change would have a negative impact on the individual market risk pool, because most applicable enrollees would be seeking to change coverage based on financial rather than health needs. However, we sought comment on concerns about adverse selection risk with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether this risk would be significantly lower if we only permitted an enrollee to change to a plan one metal level lower than their current QHP. We also requested comment from issuers on whether there were concerns about impacts such as experiencing a decrease in premium receipts from enrollees who opted to change to a lower-cost plan, or whether they view adverse selection as a possibility.

Additionally, we solicited comments on the extent to which Exchanges would experience burden due to the proposed change, and on whether we should exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether to help to mitigate this burden, or whether such a change would significantly increase risk for adverse selection.

Finally, we solicited comment on whether this change to current system logic would impose burden on FFE Direct Enrollment and Enhanced Direct Enrollment partners, as well as more generally, on the impact of this proposal.

We received public comments on the potential risk related to the proposed updates to add new flexibility to allow current Exchange enrollees and their dependents to enroll in a new QHP of a lower metal level if they qualify for a special enrollment period due to becoming newly ineligible for APTC. The following is a summary of the comments we received and our responses.

Comment: Almost all comments on this proposal were supportive of this change, for the same reasons that HHS proposed the policy: allowing enrollees the flexibility to change to a plan of a lower metal level based on a loss of APTC will likely allow more individuals to maintain

continuous coverage. No commenters raised concerns that this policy would increase the risk of adverse selection. One commenter encouraged us to bear in mind the risks of adverse selection in general, but did not oppose this proposal and noted that it would help consumers. Some commenters also noted that this proposal could improve the individual market risk pool by increasing the likelihood that Exchange enrollees would maintain coverage in spite of losing financial assistance. No commenters raised concerns about receiving lower premium payments from enrollees who opted to change to a plan of a lower metal level. Many commenters supported allowing individuals who qualify for a special enrollment period based on a loss of APTC eligibility to change to a plan of any metal level, either to provide enrollees with flexibility to change to the best plan for themselves and their families, to make implementation easier for State Exchanges, or both. One of these commenters requested that instead of applying plan category limitations, HHS require Exchange enrollees to provide documents to confirm their SEP eligibility. Some commenters supported allowing individuals who lose APTC eligibility to change to a plan of a higher or lower metal level rather than just to a plan of a lower metal level. No commenters raised concerns about this proposal's implementation burden on direct enrollment or enhanced direct enrollment partners. Finally, many commenters disagreed with the need to require plan category limitations in general, and requested that HHS provide Exchanges with flexibility in terms of when or whether to implement plan category limitations at all based on considerations related to their specific State Exchange's market.

Response: We agree with commenters that allowing enrollees to access a plan at any metal level through this existing special enrollment period, rather than only allowing them to change to a plan of a lower metal level, will significantly decrease Exchange implementation complexity and cost. As discussed earlier in the preamble, we also agree with commenters who suggested that providing more flexibility for Exchange enrollees in this situation will help them to stay enrolled in coverage by switching to a new QHP that better suits their changed financial situation. We also agree with commenters that this specific policy does not pose adverse

selection risk because enrollees are likely to access it based on a financial change as opposed to a change in their health care needs. Therefore, we are finalizing a modified version of this policy to permit Exchange enrollees who lose APTC eligibility to change to a new plan at any metal level, and to require that Exchanges implement this change no later than January 1, 2024 to provide them with potentially necessary time to account for this change in their operational planning. While some Exchanges may be able to implement this new flexibility sooner than January 1, 2024, in light of competing priorities such as the need to implement changes to calculate financial assistance established in the American Rescue Plan Act of 2021, we believe that substantial flexibility for Exchanges is appropriate.

We also clarify that this policy does not create a new special enrollment period qualifying event, but rather is a change to limitations on plan selection that apply to an already-existing special enrollment period for Exchange enrollees who become newly ineligible for APTC per 45 CFR 155.420(d)(6)(i) and (ii).

We did not propose removing plan category limitations. We will continue to study potential policies to promote continuous coverage and provide consumers with flexibility. Finally, we acknowledge the potential benefit of requiring Exchanges to implement this change quickly, but we believe that providing Exchanges with flexibility to implement it no later than January 1, 2024 strikes an appropriate balance between allowing early implementation if possible and providing Exchanges with necessary flexibility to plan related system updates based on Exchange-specific competing priorities and resources, such as implementation of changes to eligibility for advance payments of the premium tax credit established by the American Rescue Plan Act of 2021.

b. Special enrollment periods – untimely notice of triggering event

We anticipate that the amendments related to qualified individuals who do not receive timely notice of a triggering event and otherwise are reasonably unaware that a triggering event occurred will provide certain consumers a pathway to maintain continuous coverage, which will

have an overall positive impact on the risk pool and will benefit consumers. Consumers will benefit from being able to maintain continued access to coverage and health care. We recognize the possibility of some minor adverse selection risk given that consumers with known health issues may be more likely to request a retroactive effective date than healthy consumers. However, we expect this risk to be very limited as the proposal only permits individuals to request a retroactive effective date if they did not receive timely notice of a triggering event, and we do not expect this to happen very often.

We expect that Exchanges and direct enrollment partners might incur minor costs to update consumer messaging and processes to administer this proposal. State Exchanges that currently do not have this policy and issuers offering off-Exchange plans would incur minor costs to implement this proposal.

We received public comments on the proposed updates to Special Enrollment Periods – Untimely Notice of Triggering Event. See the preamble to this provision for a summary of the comments we received and our responses.

c. Cessation of employer contributions and government subsidies to COBRA as special enrollment period trigger

We anticipate that the amendments regarding special enrollment period eligibility for qualified individuals whose employers completely cease payment of their portion of COBRA continuation coverage premiums will provide clarity regarding a policy that has been operationalized on HealthCare.gov. In addition, we believe that specifying that cessation of government subsidies to COBRA is also a special enrollment period triggering event will help make stakeholders aware of the options consumers have for enrolling through a special enrollment period. We also believe that these amendments will benefit direct enrollment partners and employers by providing clarity regarding special enrollment period eligibility. In addition, consumers who would have otherwise lost coverage due to an increase in the cost of their

COBRA continuation coverage will benefit from continuity of coverage and access to health care.

Although this special enrollment period has already been available to individuals enrolling in a qualified health plan on Exchanges on the Federal Platform, because cessation of government subsidies to COBRA has not previously been considered a triggering event, we do anticipate that the Exchanges on the Federal platform, direct enrollment partners, State Exchanges that do not have this policy, and issuers who operate off-Exchange plans will incur some costs to implement this policy, especially in light of the projected increase in COBRA enrollments as a result of the subsidies provided for in the American Rescue Plan Act of 2021.³⁴⁴ However, due to the similarity between cessation of employer contributions to COBRA, which has already been a special enrollment period trigger on Exchanges on the Federal platform, and government subsidies, we do not believe these amendments will have a negative impact on the risk pool for Federally-facilitated Exchanges. However, we do anticipate that there may be some negative impact to the risk pool in State Exchanges and in the off-Exchange individual market where this special enrollment period has not previously been available.

We received public comments on the proposed updates to cessation of employer contributions to COBRA as special enrollment period trigger. The following is a summary of the comment we received and our response.

Comment: One commenter, while not opposing the proposal, expressed concern regarding the potential impact on adverse selection and premium costs of providing a pathway for those who were enrolled in COBRA continuation coverage to enroll in individual market coverage, given the likelihood of this population having increased claims. In addition, this commenter expressed concern that the requirements of this proposal would be burdensome for

³⁴⁴ <https://www.cbo.gov/system/files/2021-02/hEdandLaborreconciliationestimate.pdf>. These projections from the CBO reference an earlier version of the legislation in which enrollees would have been required to pay 15 percent of the COBRA premium, whereas the final version that was passed subsidizes COBRA premiums at 100 percent. Thus these projections may underestimate the increase in enrollments in COBRA as a result of the subsidies.

employers, as they would need to make changes to current COBRA administration procedures in order to be able to verify eligibility for this special enrollment period. They also noted that the existence of this special enrollment period could reduce the number of employers willing to provide COBRA subsidies as part of a severance package. Another commenter expressed support for the proposal, and stated that because the special enrollment period is based on reduced affordability of coverage rather than a health condition, it avoids concerns regarding adverse selection, and in fact will likely benefit the risk pool overall by encouraging younger individuals to enroll. A State Exchange noted that, because loss of COBRA coverage is used infrequently as a triggering event on its State Exchange, this policy would be unlikely to impact premium costs or the risk pool.

Response: We note that enrollments through this special enrollment period based on cessation of employer contributions to COBRA has already been available on Exchanges on the Federal platform, and thus this policy is unlikely to result in changes for issuers on such Exchanges as a result of adverse selection or for consumers in the form of premium increases. In addition, for State Exchanges and off-Exchange issuers who have not treated cessation of employer contributions to COBRA continuation coverage as a special enrollment period triggering event, we expect, based on a recent CBO analysis projecting low overall enrollment in COBRA among the eligible population,³⁴⁵ as well as the comment on this provision from a State Exchange noting that loss of COBRA coverage is used infrequently as a triggering event on its Exchange, that the volume of enrollments through this special enrollment period based on cessation of employer contributions will be low. However, the inclusion of government subsidies to COBRA coverage as a special enrollment period trigger may lead to an increase in uptake of COBRA coverage among the eligible population, and a corresponding increase in enrollments through this special enrollment period for Exchanges using the Federal platform, State

³⁴⁵ <https://www.cbo.gov/system/files/2021-02/hEdandLaborreconciliationestimate.pdf>.

Exchanges, and off-Exchange issuers, and thereby have a negative impact on these risk pools and on premiums.

The aforementioned CBO analysis notes however that many of the enrollees who are projected to enroll in COBRA as a result of the federal subsidies would have otherwise enrolled in individual market coverage,³⁴⁶ thus limiting the potential negative impact. Additionally, because this provision does not impose any new requirements on employers or increase the opportunity to enroll in employer-sponsored coverage, it is unlikely that it will discourage them from providing COBRA subsidies as part of a severance package, nor is it likely to provide additional administrative burden. Because this special enrollment period provides a pathway to individual health insurance coverage for individuals whose employer ceases contributions to their COBRA coverage, this provision may, in fact, increase the number of employers willing to provide contributions to former employees' COBRA coverage.

9. Provisions Related to Cost Sharing (§ 156.130)

As described earlier in the preamble, we are finalizing a premium adjustment percentage of 1.3760126457 for the 2022 benefit year. The annual premium adjustment percentage is used to set the rate of increase for several parameters detailed in the ACA, 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 2022 benefit year.

In accordance with § 155.605(d)(2), we are finalizing a required contribution of 8.09 percent for the 2022 benefit year, which reflects the premium adjustment percentage calculation for the 2022 benefit year detailed in preamble. In accordance with § 156.130(a)(2), we are finalizing a maximum annual limitation on cost sharing of \$8,700 for self-only coverage and

³⁴⁶ <https://www.cbo.gov/system/files/2021-02/hEdandLaborreconciliationestimate.pdf>.

\$17,400 for other than self-only for the 2022 benefit year. The CMS Office of the Actuary estimates that the change in measure of premium growth from using private health insurance (excluding Medigap, and property and casualty insurance) to ESI to calculate the premium adjustment percentage may have the following impacts between 2022 and 2026.³⁴⁷

TABLE 15: Impacts of Modifications to the 2022 Benefit Year Premium Adjustment Percentage

Calendar Year	2022 ³⁴⁸	2023	2024	2025	2026
Exchange Enrollment Impact (enrollees, thousands)	0	20	20	20	20
Premium Impacts					
Gross Premium Impact (change from 2018 %)	0%	0%	0%	0%	0%
Net Premium Impact (change from 2018, %)	0%	0%	-1%	-1%	-1%
Federal Impacts (dollars, millions)					
Premium Tax Credits (million, \$)*	0	460	480	490	510

*Note: The federal impact figures are positive to indicate an increase in spending for the federal government.

As noted in Table 15, we expect that the change in measure of premium growth used to calculate the premium adjustment percentage index for the 2022 benefit year and beyond will likely result in:

- Net premium decreases of approximately \$181 million per year, which is approximately one percent of 2018 benefit year net premiums, for the 2024 benefit year through the 2026 benefit year.
- An increase in federal premium tax credit spending of \$460 million to \$510 million between 2023 and 2026, due to the decrease in the applicable percentage table, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the NHEA ESI premium measure finalized for the calculation of the premium

³⁴⁷ 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.

³⁴⁸ The American Rescue Plan Act of 2021 Pub L. 117-2 (3/11/2021) amends Section 36B(b)(3)(A) of the Internal Revenue Code of 1986 to lower the applicable percentage for taxpayers at all FPL levels, and includes taxpayers with an income of 400 percent FPL or higher to be eligible for premium tax credits. The effects of the American Rescue Plan Act of 2021 are expected to supplant the economic impacts of finalizing the premium adjustment percentage and cost-sharing parameters using the NHEA ESI premium measure for the 2022 benefit year.

adjustment percentage in this rule for the purposes of calculating the indexing of the premium tax credit applicable percentage and required contribution percentage under section 36B of the Code.

We are also finalizing the proposed rates of reductions to the maximum annual limitation on cost sharing of 2/3 for enrollees with a household income between 100 and 200 percent of FPL, 1/5 for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond. We are finalizing the proposed methodology to ensure that these reductions do not result in unacceptably high AVs. We do not anticipate that the rates of reduction and the methodology will result in significant economic impact because these rates of reduction and the AV-impact testing methodology have remained consistent since the 2014 Payment Notice.

We are also finalizing that beginning with the 2023 benefit year, we will publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitations on cost sharing, and required contribution percentage in guidance in January of the calendar year preceding the benefit year to which the parameters are applicable, unless HHS is changing the methodology, in which case we will do so through the applicable HHS notice of benefit and payment parameters. This policy change affects only the timing and method by which these parameters are released and will provide issuers with additional time for plan design and rate setting.

10. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

As part of the ACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a

state under section 1311 of the ACA³⁴⁹ to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section 1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.³⁵⁰

On January 1, 2020³⁵¹ and on September 11, 2020,³⁵² we published notices in the **Federal Register** and solicited public comment on the burden related to the collection of information required by section 1150A of the Act. In those information collections and in this final rule, we fulfill this statutory requirement with the goal of imposing the least amount of burden possible while collecting data that would be usable to ensure increased transparency on prescription drug coverage in QHPs.

For example, to reduce overall burden, we will collect data directly from PBMs that contract with QHPs directly, rather than require QHP issuers to serve as a go-between their PBM and CMS.³⁵³ This approach will reduce overall burden on QHP issuers and will place the onus to report data on those entities that QHP issuers have already entrusted to oversee and manage their prescription drug line of business.

These information collections also explained how we utilize the reporting paradigm currently used by CMS' DIR reporting requirement which collects, in part, the data required by

³⁴⁹ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the ACA. *King v. Burwell*, 576 U.S. 988 (2015).

³⁵⁰ The purposes are: as the Secretary determines to be necessary to carry out section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the ACA.

³⁵¹ 85 FR 4993 through 4994.

³⁵² 85 FR 56227 through 56229.

³⁵³ Under this interpretation, QHP issuers will be required to report data directly to CMS only when the QHP issuer does not contract with a PBM to administer their drug benefit.

section 1150A(a)(1) of the Act from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVII. We noted our intention to utilize the DIR reporting mechanisms only to the extent authorized solely by section 1150A(a)(2), explaining our understanding that DIR reporting is not authorized by section 1150A alone.³⁵⁴ Usage of these existing CMS reporting paradigms ensures minimal impact of a new data collection on QHP issuers and PBMs, given the longstanding industry use of the DIR reporting mechanism. The payer community is familiar with fulfilling the DIR reporting requirement. Therefore, we believe replicating that collection to the greatest degree will enable respondents to implement this data collection with minimal relative burden.

11. Audits of APTC, CSRs, and User Fees (§ 156.480(c))

We are providing more clarity around the APTC, CSR, and user fee program audits and establishing authority for HHS to conduct compliance reviews to assess compliance with federal APTC, CSR, and user fee standards by finalizing amendments to § 156.480(c), with slight modifications to certain audit timeframes in response to comments requesting issuers be provided more time to provide the initial audit data submissions and written corrective action plans. QHP issuers being audited for compliance with federal APTC, CSR, and user fee standards will be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. We are also codifying our authority to recoup APTC and CSR payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

³⁵⁴ Except for PBM spread amount aggregated to the plan benefit package level, section 1150A imposes no additional reporting requirements for entities subject to DIR reporting. See 77 FR 22094.

We anticipate that compliance with APTC, CSR, and user fee program audits will take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$14,356. While the number of QHP issuers participating in the APTC, CSR, and user fee programs varies per benefit year (for example, there were 561 QHP issuers participating in the programs for the 2019 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30-60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited will be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

We anticipate that APTC, CSR, and user fee program compliance reviews will take 30 hours by a business operations specialist (at a rate of \$77.14 per hour), 10 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 5 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,589. While the number of QHP issuers participating in the APTC, CSR, and user fee programs varies per benefit year, (for example, there were 561 QHP issuers participating in the programs for the 2019 benefit year), HHS only intends to conduct compliance reviews for no more than 15 issuers per benefit year. The total annual cost to issuers undergoing compliance reviews will be approximately \$53,836.

12. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

We are finalizing removal of the composite level and domain level of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We will also make the full QHP Enrollee Survey results publicly available in an annual PUF. We anticipate that these changes will benefit consumers and QHP issuers by increasing transparency and availability of QHP survey data

through publication of a nationwide PUF, and simplifying the QRS scoring hierarchy to improve understanding of QRS quality rating information and alignment with other CMS quality reporting programs. Neither refinement will alter the data collection and reporting requirements for the QRS and QHP Enrollee Survey because QHP issuers are already required to report all data needed to support a QHP Enrollee Survey PUF and simplified QRS hierarchy. Therefore, these refinements will create no additional cost or burden for QHP issuers.

13. Medical Loss Ratio (§§ 158.103, 158.130, 158.240, and 158.241)

We are finalizing the proposal to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i). We do not expect this to change the result of the regulatory impact analysis previously conducted for the 2021 Payment Notice with respect to the requirement that issuers deduct from MLR incurred claims not only prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer and any prescription drug rebates and other price concessions received and retained by a PBM or other entity providing pharmacy benefit management services to the issuer.

We are also finalizing the proposal that issuers that choose to provide temporary premium credits to consumers during a declared PHE in 2021 and beyond when permitted by HHS must account for these credits as reductions to premium for the applicable months when reporting earned premium for the applicable MLR reporting year. Although we do not know how many states will permit issuers to provide temporary credits to reduce premiums or how many issuers will elect to do so, for purposes of this analysis, we previously estimated in the interim final rule on COVID-19 (85 FR 54820) that approximately 40 percent of issuers offering individual, small group or merged market health insurance coverage will provide these premium credits to reduce the premiums charged to enrollees to support continuity of coverage during the PHE for COVID-19. We do not estimate a change to the cost or burden previously estimated in

that final rule, and anticipate that that regulatory impact estimate would extend to 2021 and beyond. Although we do not know the number of issuers that will provide these temporary premium credits or the amount of premium credits that issuers may elect to provide, for purposes of this estimate we assume that such premium credits will on average constitute approximately 8 percent of total annual premium (equivalent to one month of premium), as previously estimated in that final rule. Because the MLR calculation uses three consecutive years of data, there may be additional rebate decreases in subsequent years, although the impact on rebates might be smaller as issuers will likely account for the premium relief provided to enrollees through these temporary premium credits at the time they develop premium rates for the 2022 benefit year and future benefit years.

As noted in section IV of this final rule, on March 4, 2021, the U.S. District Court for the District of Maryland, in *City of Columbus, et al. v. Cochran*, vacated 45 CFR 158.221(b)(8). As a result, we are finalizing the deletion of § 158.221(b)(8) and removing the option that issuers had for the 2017-2019 MLR reporting years to report a single standardized QIA expense amount equal to 0.8 percent of earned premium in lieu of reporting the issuers' actual expenditures for activities that improve health care quality. The 0.8 percent QIA option was added to 45 CFR part 158 in the 2019 Payment Notice final rule in order to reduce the burden on issuers required to accurately identify, track, and report QIA expenses. In that final rule, based on MLR data for the 2015 MLR reporting year, HHS estimated that the amendment would decrease rebate payments from issuers to consumers by approximately \$23 million. Accordingly, we estimate that finalizing the deletion of § 158.221(b)(8) in this final rule will increase rebate payments from issuers to consumers by approximately \$23 million annually.

We are also finalizing the proposal to add a new § 158.240(g) to explicitly allow issuers to prepay a portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. We are

additionally finalizing the proposal to amend § 158.241(a) to allow issuers to provide rebates in form of a premium credit prior to the date that the rules previously provided. We do not expect these provisions to have a significant quantitative impact as they will not change the rebate amounts provided by issuers to enrollees. Since it is easiest and most cost-effective for issuers to conduct rebate disbursement activities all at once, the additional rebates will generally be paid during the following year's disbursement cycle – that is, if 95 percent of rebates for 2020 was prepaid during Jan.-July 2021, the remainder will be paid no later than Sept. 2022 (possibly earlier in 2022 if the issuer decides to prepay again). However, we note that there may be some increased administrative burden on issuers that owe rebates remaining after prepayment associated with good faith efforts to locate enrollees, if any, with whom they no longer have a direct economic relationship.

14. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that this rule will be reviewed by all affected issuers, states, PBMs, and some individuals and other entities that commented on the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of affected entities and commenters to be a fair estimate of the number of reviewers of this rule.

We are required to issue a substantial portion of this rule each year under our regulations and we estimate that approximately half of the remaining provisions would 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 rule is \$110.74 per hour, including overhead and fringe benefits.³⁵⁵ Assuming an average reading speed, we estimate that it will take approximately 1 hours to review the relevant portions of this final rule that causes unanticipated burden. We assume that 750 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately \$110.74. Therefore, we estimate that the total cost of reviewing this regulation is approximately \$83,055 (\$110.74 x 750 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

Under part 153 of this final rule, we are finalizing an approach to recalibrate the risk adjustment models for the 2022 benefit year using 2016, 2017, and 2018 enrollee-level EDGE data.³⁵⁶ The purpose of using these data years is to better ensure that the applicable benefit year's risk adjustment model coefficients can be included in the applicable benefit year's proposed payment notice. As part of our consideration of proposals to recalibrate the risk adjustment models for the 2022 benefit year, we also considered recalibrating the models using the 2017, 2018, and 2019 benefit year enrollee-level EDGE data. If we had proposed that approach, we would not have been able to provide the proposed coefficients in the proposed rule and would have had to instead display draft coefficients only reflective of the 2017 and 2018 benefit years of enrollee-level EDGE data. This approach would not have achieved the desired policy goals –

³⁵⁵ https://www.bls.gov/oes/current/oes_nat.htm.

³⁵⁶ As detailed above, the one exception relates to RXC 09, which involved the use of only 2016 and 2017 enrollee-level data to develop the applicable 2022 benefit year coefficients and interaction terms.

namely, to respond to stakeholder requests for HHS to take steps to provide the draft and final coefficients at an earlier time.

We also considered alternatives to the proposed model specification changes and revised enrollment duration factors that we are not finalizing in this rulemaking. For example, we initially considered adding only a non-linear term or only adopting new HCC counts terms for all enrollees to the adult and child risk adjustment models. As described earlier in this final rule, we had convergence issues with the non-linear model specifications and concerns that the HCC counts terms approach posed significant gaming concerns when pursued separately.

In addition to the non-linear and HCC counts model specifications, we also considered alternatives to the two-stage specification and HCC interacted counts model. Specifically, we tested various alternative caps for the weights based on the distribution of costs, but found the finalized caps resulted in better prediction on average. For the prediction weights, we tested various alternative forms of weights, including reciprocals of square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of the other weights.

For the interacted HCC counts factors, we tested several HCCs and considered adding and removing certain HCCs from the list in Table 3 in the proposed rule. We choose the list of HCCs in Table 3 of the proposed rule because including those HCCs most improved prediction for enrollees with the highest costs, multiple HCCs, and with these specific HCCs. For the HCC interacted counts, we also considered various alternatives to structure the interacted HCC counts, such as applying individual interacted HCC counts factors (between 1-10 based on the number of HCCs an enrollee has) to each of the selected HCCs included in the models (instead of combining all of the selected HCCs into two severity and transplant indicator groups). We choose the proposed model specifications because they would add fewer additional factors to the models without sacrificing any significant predictive accuracy. However, as noted above, after consideration of comments, we are not finalizing the adoption of either the proposed two-

stage model specification or interacted HCC counts factors in the adult and child models or the accompanying removal of the existing severity illness indicators from the adult models.

For the enrollment duration factors in the adult risk adjustment models, we proposed modifying the enrollment duration factors to apply monthly duration factors of up to 6 months for those with HCCs. The purpose of this proposed change was to address the underprediction of plan liability for adults with HCCs. As part of this assessment, we considered whether enrollment duration factors by market type may be warranted. However, as described earlier in this final rule, we did not find a major distinction in market-specific incremental monthly enrollment duration factor risk scores after isolating the enrollment duration factors to enrollees with HCCs. However, as detailed above, after consideration of comments, we are not finalizing the adoption of the new proposed adult model enrollment duration factors or the accompanying removal of the current adult model enrollment duration factors.

In regards to the changes to § 155.320, we considered taking no action to modify the requirement that when an Exchange does not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage that the Exchange must select a statistically significant random sample of applicants and attempt to verify their attestation with the employer listed on their Exchange application. However, based on HHS's experience conducting sampling, this manual verification process requires significant resources for a low return on investment, as using this method HHS identified only a small population of applicants who received APTC/CSR payments inappropriately. We ultimately determined that a verification process for employer-sponsored coverage should be one that is evidence or risk-based and that not taking enforcement action against Exchanges that do not conduct random sampling was appropriate as we anticipate future rulemaking is necessary to ensure that Exchanges have more flexibility for such verifications.

We considered taking no action regarding our policy to add a new § 155.420(a)(4)(iii)(C) to allow enrollees and their dependents to enroll in a new QHP of a lower metal level³⁵⁷ if they qualify for a special enrollment period due to becoming newly ineligible for APTC. However, based on questions and concerns from agents and brokers, the previous policy prevents some enrollees from maintaining continuous coverage because they lose a significant amount of financial assistance that would help them purchase coverage, and cannot enroll in a new, less costly QHP of a lower metal level. HHS believes this policy is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium.

We also considered whether to provide additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with section 155.420(d)(6)(i) or (ii) to enroll in a QHP of a higher metal level, because we recognize becoming newly eligible for APTC may increase the affordability of higher metal level plans for some individuals. However, as discussed in the proposed rule, we believed including this flexibility would largely exempt the special enrollment periods at paragraph (d)(6)(i) and (ii) from the rules at 155.420(a)(4)(iii), which might make it likely that more individuals would change coverage levels in response to health status changes. More importantly, while we believe the flexibilities for individuals who become newly ineligible for APTC are needed in order to promote continuous coverage for individuals who can no longer afford their original plan choice, no similar affordability and continuous coverage concerns exist for enrolled consumers who gain APTC eligibility during the coverage year. However, as noted in preamble, we received several comments requesting that HHS provide this flexibility for enrollees who newly become eligible for APTC. Therefore,

³⁵⁷ Section 1302(d) of the ACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the ACA. Consumer-facing HealthCare.gov content explains that metal levels serve as an indicator of “how you and your plan split the costs of your health care,” noting that lower levels like bronze plans have lower monthly premiums but higher out of pocket costs when consumers access care, while higher levels like gold have higher monthly premiums but lower out of pocket costs to access care – see <https://www.healthcare.gov/choose-a-plan/plans-categories/>.

while we did not propose additional plan flexibility for enrollees who become newly eligible for APTC, we will continue to study potential policies to promote continuous coverage and provide consumers with flexibility.

We considered taking no action regarding our policy to add a new § 155.420(c)(5) to allow a qualified individual, dependent or enrollee that did not receive timely notice of a triggering event or was otherwise reasonably unaware that a triggering event described in § 155.420(d) occurred to select a new plan within 60 days of the date he or she knew, or reasonably should have known, of the occurrence of the triggering event. However, in some circumstances this would result in consumers, through no fault of their own, being unable to access a special enrollment period for which they were eligible. Additionally, we considered not adding new § 155.420(b)(5) to provide a qualified individual, dependent, or enrollee described in new § 155.420(c)(5) with the option for a retroactive effective date. Failing to provide the option for a retroactive effective date would necessarily result in a gap in coverage, and therefore hinder a consumer's ability to maintain continuous coverage.

We also considered limiting the applicability of the policy to add a new § 155.420(c)(5) to a qualified individual, enrollee, or dependent who does not receive notice or become reasonably aware of the occurrence of a triggering event until more than 15 days after the triggering event. However, failing to apply the new § 155.420(c)(5) to qualified individuals, enrollees, or dependents who receive notice or become reasonably aware of the occurrence of a triggering event 15 days or less after the triggering event and eliminating the option for a retroactive effective date for those individuals would result in a gap in coverage for such individuals and hinder their ability to maintain continuous coverage.

We considered taking no action regarding our policy to add new paragraph (d)(15) to § 155.420 to specify that complete cessation of employer contributions or government subsidies to COBRA continuation coverage is a special enrollment period triggering event. However, codifying this policy in regulation provides transparency to a long-standing interpretation of the

Exchanges on the Federal platform. Additionally, codifying this policy in regulation ensures alignment across all Exchanges and in the off-Exchange individual market.

For the revisions to § 156.295 and addition of § 184.50 to require certain prescription drug reporting, we considered, but did not yet require, the reporting of data described in section 1150A(b)(1) broken down by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). As mentioned in this final rule, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files. While we believe the imposition of this level of reporting would impose unreasonable burden at this time, we intend to begin collecting this information in the future.

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 final rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this rule, we finalize standards for the risk adjustment program, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. 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 \$41.5

million or less are 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 \$35 million or less.³⁵⁸ 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 report³⁵⁹ submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 67 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 \$41.5 million. Therefore, we do not expect the provisions of this rule to affect a substantial number of small entities.

In this rule, we are requiring certain QHP issuers or their PBMs to report certain prescription drug information to CMS. We are not aware of any QHP issuer or PBM that contracts with a QHP issuer to administer their prescription drug benefit which would be considered a “small entity” under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under title XVIII, title XIX, or part B of title 42 of the Act 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. While this rule is not subject to section 1102 of the Act, we have determined that this rule will not affect small rural hospitals. Therefore, the Secretary has

³⁵⁸ <https://www.sba.gov/document/support--table-size-standards>.

³⁵⁹ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

determined that this rule 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 final rule that includes any federal mandate that may result in expenditures in any one 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 2021 that threshold is approximately \$158 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 final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. In our view, while this final rule will not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets.

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 NAIC, and consulting with state insurance officials on an individual basis.

While developing this rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we 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, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating 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. A user fee is assessed on issuers under all existing Exchange models, including State Exchanges where the user fee is assessed by the state, SBE-FPs, and the FFEs.

H. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, et seq.), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review. Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs designated this final rule as a “major rule” as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of \$100 million or more.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 21, 2021.

List of Subjects

45 CFR Part 147

Age discrimination, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 150

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Age discrimination, Brokers, Civil rights, Citizenship and naturalization, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, 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, Sex discrimination, State and local governments, Technical assistance, Taxes, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, 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, Intergovernmental relations, Loan programs-health, Medicaid,

Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 184

Administrative practice and procedure, Consumer protection, Health care, Health insurance, Health maintenance organization (HMO), Organization and functions (Government agencies), Prescription Drugs, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 147 – HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

1. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

2. Section 147.104 is amended by revising paragraphs (b)(2)(ii) and (4)(ii) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(2) * * *

(ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in §§ 155.420(a)(5) and (d)(4)) of this subchapter to a “QHP” is deemed to refer to a plan, a reference to “the Exchange” is deemed to refer to the applicable State authority, and a reference to a “qualified individual” is deemed to refer to an individual in the individual market. For purposes of § 155.420(d)(4) of this subchapter, “the Exchange” is deemed to refer to the Exchange or the health plan, as applicable.

* * * * *

(4) * * *

(ii) In the individual market, subject to § 155.420(c)(5) of this subchapter, individuals must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in § 155.420(c)(2) of this subchapter.

PART 150 – CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

3. The authority citation for part 150 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92, as amended.

§ 150.103 [Amended]

4. In § 150.103, amend the definition of “Complaint” by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.205 [Amended]

5. In § 150.205, amend paragraph (e)(2) by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.213 [Amended]

6. In § 150.213, amend paragraph (b) by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.303 [Amended]

7. In § 150.303, amend paragraph (a) introductory text by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.305 [Amended]

8. In § 150.305, amend paragraphs (a)(1), (a)(2), (b)(1), and (c)(1) by removing the word “HIPAA” each time it appears and adding in its place “PHS Act”.

§ 150.311 [Amended]

9. In § 150.311, amend paragraph (g) by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.313 [Amended]

10. In § 150.313, amend paragraph (b) by removing the word “HIPAA” and adding in its place “PHS Act”.

11. Amend § 150.401 by revising the definitions of “Filing date” and “Hearing” to read as follows:

§ 150.401 Definitions.

* * * * *

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

* * * * *

§ 150.419 [Amended]

12. In § 150.419, amend paragraph (a) by removing the phrase “or by telephone” and adding in its place the phrase “by telephone, or by video teleconference”.

13. Amend § 150.427 by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 150.427 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

14. Revise § 150.431 to read as follows:

§ 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions

for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

15. Amend § 150.441 by revising paragraph (e) to read as follows:

§ 150.441 Prehearing conferences.

* * * * *

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

* * * * *

§ 150.447 [Amended]

16. In § 150.447, amend paragraph (a) by removing the phrase “or by telephone” and adding in its place the phrase “by telephone, or by video teleconference”.

PART 153 – STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

17. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

18. Section 153.320 is amended by revising paragraph (c) as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in notice-and-comment rulemaking by HHS in advance of the applicable benefit year, the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

* * * * *

19. Section 153.410 is amended by revising paragraph (d) to read as follows:

§ 153.410 Requests for reinsurance payment.

* * * * *

(d) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described in paragraph (d)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (d)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (d)(2)(ii) or (iii) of this section, as

applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of reinsurance payments received that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (5)(i) of this section.

20. Section 153.620 is amended by revising paragraph (c) to read as follows:

§ 153.620 Compliance with risk adjustment standards.

* * * * *

(c) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with respect to the applicable requirements in this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the audit entrance conference described in paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraphs (c)(2)(ii) or (iii) of this section, as

applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of the risk adjustment (including high-cost risk pool) payments that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any risk adjustment (including high-cost risk pool) payments identified in paragraph (c)(5)(i) of this section.

21. Section 153.630 is amended by—

- a. Revising paragraph (d)(3); and
- b. Adding paragraphs (g)(4) and (5).

The revisions read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * *

(d) * *

(3) An issuer may appeal the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as result of risk adjustment data validation, under the process set forth in § 156.1220 of this subchapter.

* * * *

(g) * *

(4) The issuer only offered small group market carryover coverage during the benefit year that is being audited.

(5) The issuer was the sole issuer in the state market risk pool during the benefit year that is being audited and did not participate in any other market risk pools in the State during the benefit year that is being audited.

22. Section 153.710 is amended—

a. By redesignating paragraphs (e) through (g), as paragraphs (f) through (h), respectively;

b. By adding a new paragraph (e); and

c. In newly redesignated paragraph (h) introductory text by removing the reference “paragraph (g)(3)” and adding in its place the reference “paragraph (h)(3)”.

The addition reads as follows:

§ 153.710 Data requirements.

* * * *

(e) *Materiality threshold.* HHS will consider a discrepancy reported under paragraph (d)(2) of this section to be material if the amount in dispute is equal to or exceeds 1 percent of

the applicable payment or charge payable to or due from the issuer for the benefit year, or \$100,000, whichever is less.

* * * * *

PART 155 – EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

23. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083.

24. Section 155.20 is amended by--

a. Adding, in alphabetical order, the definition of “Agent or broker direct enrollment technology provider”;

b. Removing the definition of “Direct enrollment technology provider”;

c. Adding, in alphabetical order, the definition of “Qualified health plan issuer direct enrollment technology provider”;

c. Revising the definition of “Web-broker”.

The additions and revision read as follows:

§ 155.20 Definitions.

* * * * *

Agent or broker direct enrollment technology provider means a type of web-broker business entity that is not a licensed agent or broker 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.

* * * * *

Qualified health plan issuer direct enrollment technology provider means a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 or

156.1230, including a web-broker that provides services as a direct enrollment technology provider to QHP issuers. A QHP issuer direct enrollment technology provider that provides technology services or provides access to an information technology platform to a QHP issuer will be a downstream or delegated entity of the QHP issuer that participates or applies to participate as a direct enrollment entity.

* * * * *

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 QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221. The term also includes an agent or broker direct enrollment technology provider.

25. Section 155.205 is amended by revising paragraphs (c)(2)(i)(B), (c)(2)(iii)(B), (c)(2)(iv) introductory text, and (c)(2)(iv)(C) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(B) For a web-broker, beginning November 1, 2015, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, this standard also includes telephonic interpreter services in at least 150 languages.

* * * * *

(iii) * * *

(B) For a web-broker, beginning when such entity has been registered with the Exchange for at least 1 year, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a

QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Web site content or documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if they are required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. A web-broker that is licensed in and serving multiple States may aggregate the limited English populations in the States it serves to determine the top 15 languages required for taglines. A web-broker may satisfy tagline requirements with respect to Web site content if it posts a Web link prominently on its home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if it also includes taglines on any critical stand-alone document linked to or embedded in the Web site.

(iv) For Exchanges, QHP issuers, and web-brokers, Web site translations.

* * * * *

(C) For a web-broker, beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a Web site that is maintained by the web-broker must be translated into any non-English language that is spoken by a limited English proficient population that comprises 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

* * * * *

26. Section 155.220 is amended by adding paragraph (c)(6) to 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.

* * * *

(c) * *

(6) In addition to applicable requirements under § 155.221(b)(4), a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's internet Web site being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

(i) Operational data including licensure information, points of contact, and third-party relationships;

(ii) Enrollment testing, prior to approval or renewal;

(iii) Website reviews performed by HHS;

(iv) Security and privacy assessment documentation, including:

(A) Penetration testing results;

(B) Security and privacy assessment reports;

(C) Vulnerability scan results;

(D) Plans of action and milestones; and

(E) System security and privacy plans.

(v) Agreements between the web-broker and HHS.

* * * *

27. Section 155.221 is amended—

a. By revising paragraphs (b)(1), (3), and (4);

b. By redesignating paragraphs (c) through (h) as paragraphs (d) through (i), respectively.

c. By adding new paragraph (c); and

d. By amending newly redesignated paragraphs (g) introductory text, (g)(6), (g)(7), and (h) by removing the reference to “paragraph (e)” and adding in its place a reference to “paragraph (f)”.

The additions and revisions read as follows:

§ 155.221 Standards for direct enrollment entities and for third parties to perform audits of direct enrollment entities.

* * * * *

(b) * * *

(1) Display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products, such as excepted benefits, on at least three separate website pages on its non-Exchange Web site, except as permitted under paragraph (c) of this section;

* * * * *

(3) Limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under paragraph (c)(1) of this section;

(4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet Web site being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

(i) Business audit documentation including:

(A) Notices of intent to participate including auditor information;

(B) Documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and

- (C) Business audit reports including testing results.
- (ii) Security and privacy audit documentation including:
 - (A) Interconnection security agreements;
 - (B) Security and privacy controls assessment test plans;
 - (C) Security and privacy assessment reports;
 - (D) Plans of action and milestones;
 - (E) Privacy impact assessments;
 - (F) System security and privacy plans;
 - (G) Incident response plans; and
 - (H) Vulnerability scan results.
- (iii) Eligibility application audits performed by HHS;
- (iv) Online training modules offered by HHS; and
- (v) Agreements between the direct enrollment entity and HHS.

* * * * *

(c) *Exceptions to direct enrollment entity display and marketing requirement.* For the Federally-facilitated Exchanges, a direct enrollment entity may:

(1) Display and market QHPs offered through the Exchange and individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement as described in § 146.123(c) of this subchapter, as a standalone benefit, or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage health reimbursement arrangement using a salary reduction arrangement pursuant to a cafeteria plan under section 125 of the Internal Revenue Code, but must clearly distinguish between the QHPs offered through the Exchange and individual health insurance

coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicate that advance payments of the premium tax credit and cost-sharing reductions are available only for QHPs purchased through the Exchange, that advance payments of the premium tax credit are not available to individuals who accept an offer of an individual coverage health reimbursement arrangement or who opt out of an individual coverage health reimbursement arrangement that is considered affordable, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange; and

(2) Display and market Exchange-certified stand-alone dental plans offered outside the Exchange and non-certified stand-alone dental plans on the same website pages.

* * * * *

28. Effective [INSERT DATE OF PUBLICATION IN THE FEDERA REGISTER]

amend § 155.320 by—

- a. Revising paragraph (c)(3)(iii)(A); and
- b. Removing and reserving paragraphs (c)(3)(iii)(D) and (vi)(C)(2).

The revision read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(3) * * *

(iii) * * *

(A) Except as specified in paragraph (c)(3)(iii)(B) and (C) of this section, if an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(ii)(A) of this section for the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified

the applicant’s MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI- based income standard, the Exchange must accept the applicant’s attestation regarding a tax filer’s annual household income without further verification.

* * * * *

29. Section 155.420 is amended by—

- a. Revising paragraph (a)(4)(ii)(B);
- b. Adding paragraph (a)(4)(ii)(C);
- c. Revising paragraphs (a)(4)(iii) introductory text and (b)(2)(iv);
- d. Adding paragraph (b)(5);
- e. Revising paragraph (c)(2);
- f. Adding paragraphs (c)(5) and (d)(15); and
- g. Revising paragraph (e)(1).

The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(ii) * * *

(B) Beginning January 2022, if an enrollee and his or her dependents become newly ineligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a QHP one metal level higher or lower, if they elect to change their QHP enrollment; or

(C) No later than January 1, 2024, if an enrollee and his or her dependents become newly ineligible for advance payments of the premium tax credit in accordance with paragraph (d)(6)(i)

or (ii) of this section, the Exchange must allow the enrollee and his or her dependents to change to a QHP of any metal level, if they elect to change their QHP enrollment;

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (4), (6)(i) and (6)(ii) of this section for becoming newly eligible or ineligible for CSRs or, no later than January 1, 2024 newly ineligible for APTC, (d)(8), (9), (10) and (12) of this section:

* * * * *

(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, 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, or is enrolled in COBRA continuation coverage and employer contributions to or government subsidies of this coverage completely cease as described in paragraph (d)(15) 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.

* * * * *

(5) *Option for earlier effective dates due to untimely notice of triggering event.* At the option of a qualified individual, enrollee or dependent who is eligible to select a plan during a period provided for under paragraph (c)(5) of this section, the Exchange must provide the earliest

effective date that would have been available under paragraph (b) of this section, based on the applicable triggering event under paragraph (d) of this section.

(c) * * *

(2) *Advanced availability.* A qualified individual or his or her dependent who is described in paragraph (d)(1), (d)(6)(iii), or (d)(15) of this section has 60 days before or after the triggering event to select a QHP. At the option of the Exchange, a qualified individual or his or her dependent who is described in paragraph (d)(7) of this section; who is described in paragraph (d)(6)(iv) of this section and becomes newly eligible for advance payments of the premium tax credit as a result of a permanent move to a new State; or who is described in paragraph (d)(3) of this section and becomes newly eligible for enrollment in a QHP through the Exchange because he or she newly satisfies the requirements under § 155.305(a)(2), has 60 days before or after the triggering event to select a QHP.

* * * * *

(5) *Availability for individuals who did not receive timely notice of triggering events.* If a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event described in paragraph (d) of this section occurred, the Exchange must allow the qualified individual, enrollee, or when applicable, his or her dependent to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event.

* * * * *

(d) * * *

(15) The qualified individual or his or her dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, or for which a government entity is providing subsidies, and the employer completely ceases its contributions to the qualified individual's or dependent's COBRA continuation coverage or government subsidies

completely cease. The triggering event is the last day of the period for which COBRA continuation coverage is paid for or subsidized, in whole or in part, by an employer or government entity. For purposes of this paragraph, “COBRA continuation coverage” has the meaning provided for in § 144.103 of this subchapter and includes coverage under a similar State program.

(e) * * *

(1) Failure to pay premiums on a timely basis, including COBRA continuation coverage premiums prior to expiration of COBRA continuation coverage, except for circumstances in which an employer completely ceases its contributions to COBRA continuation coverage, or government subsidies of COBRA continuation coverage completely cease as described in paragraph (d)(15) of this section, or

* * * * *

PART 156 – HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

30. 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.

31. Section 156.50 is amended by—

- a. Revising the heading for paragraph (c);
- b. Revising paragraph (c)(2);
- c. Adding paragraph (c)(3);
- d. Revising the heading for paragraph (d); and
- e. Revising paragraphs (d)(1) introductory text, (d)(2) introductory text, (d)(2)(i)(A), (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3) introductory text, (d)(4) through (6), and (d)(7) introductory text.

The revisions and addition read as follows:

§ 156.50 Financial support.

* * * * *

(c) *Requirement for Exchange user fees.* ***

* * * * *

(2) To support the functions of State Exchanges on the Federal platform, unless the State Exchange and HHS agree on an alternative mechanism to collect the funds, a participating issuer offering a plan through a State Exchange on the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State Exchanges on the Federal platform for the applicable benefit year, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

(3) A participating issuer offering a plan through an State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option as described in § 155.221(j) of this subchapter, as specified in a Federal agreement with HHS, must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate for the applicable benefit year specified in an annual HHS notice of benefit and payment parameters published in advance of the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option.

(d) *Adjustment of Exchange user fees.* (1) A participating issuer offering a plan through a Federally-facilitated Exchange or State Exchange on the Federal platform may qualify for an adjustment of the Federally-facilitated Exchange user fee specified in paragraph (c)(1) of this

section, the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, or the user fee specified in paragraph (c)(3) of this section, applicable to issuers participating in a State Exchange on the Federal platform or a Federally-facilitated Exchange that has adopted the direct enrollment option under § 155.221(j) of this subchapter, the extent that the participating issuer –

* * * * *

(2) For a participating issuer described in paragraph (d)(1) of this section to receive an adjustment of a user fee under this section –

(i) * * *

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable; and

* * * * *

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federally-facilitated Exchange user fee, the State-based Exchange on the Federal platform user fee, or the user fee applicable to issuers participating in a State-based Exchange on the Federal platform or a Federally-facilitated Exchange that has adopted the direct enrollment option § 155.221(j) of this subchapter based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th

calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4).

(iii) * * *

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable;

* * * * *

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, equal in value to the sum of the following:

* * * * *

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment of a user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer

made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1), (2), or (3) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

* * * * *

32. Section 156.130 is amended by revising paragraph (e) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(e) *Premium adjustment percentage.* 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. HHS may publish the annual premium adjustment percentage in guidance in January of the calendar year preceding the benefit year for which the premium adjustment percentage is applicable, unless HHS proposes changes to the methodology, in which case, HHS will publish

the annual premium adjustment percentage in an annual HHS notice of benefit and payment parameters or another appropriate rulemaking.

* * * * *

33. Section 156.295 is amended by—

- a. Revising the section heading and paragraphs (a) introductory text, (a)(1) and (a)(2) introductory text,
- b. Removing paragraph (a)(3); and
- c. Revising paragraph (b) introductory text.

The revisions read as follows:

§ 156.295 Prescription drug distribution and cost reporting by QHP issuers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a QHP issuer that administers a prescription drug benefit without the use of a pharmacy benefit manager must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

* * * * *

(b) *Limitation on disclosure.* Information disclosed by a QHP issuer under this section shall not be disclosed by HHS, except that HHS may disclose the information in a form which does not disclose the identity of a specific QHP or prices charged for specific drugs, for the following purposes:

* * * *

34. Section 156.420 is amended by revising paragraphs (a)(1)(i), (a)(2)(i) and (a)(3)(i) to read as follows:

§ 156.420 Plan variations.

(a) * * *

(1) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * *

(2) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * *

(3) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * *

35. Section 156.480 is amended by revising the section heading and paragraph (c) to read as follows:

§ 156.480 Oversight of the administration of the advance payments of the premium tax credit, cost-sharing reductions, and user fee programs.

* * * *

(c) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer offering a QHP through an Exchange to assess its compliance with the applicable requirements of this subpart and 45 CFR 156.50. Compliance reviews conducted under this section will follow the standards set forth in § 156.715.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer under this section.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described under paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (c)(2)(ii) or (iii), as applicable, and must detail the reason for the extension request and the good cause in support of the request. If

the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit or compliance review report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this section in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of payments received under this subpart that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (c)(5)(i) of this section.

(6) *Circumstances requiring HHS enforcement.* If HHS determines that the State Exchange or State-based Exchange on the Federal platform is not enforcing or fails to substantially enforce the requirements of this subpart or §156.50, then HHS may do so and may pursue the imposition of civil money penalties as specified in § 156.805 for non-

compliance by QHP issuers participating in the State Exchange or State Exchange on the Federal platform.

Subpart I – Enforcement Remedies in the Exchanges

36. Subpart I is amended by revising the heading as set forth above.

37. Section 156.800 is amended by revising paragraphs (a) introductory text, and (b) as follows:

§ 156.800 Available remedies; Scope.

(a) *Kinds of sanctions.* HHS may impose the following types of sanctions on QHP issuers in an Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in an Exchange:

* * * * *

(b) *Scope.* Sanctions under subpart I are applicable for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange. Sanctions under paragraph (a)(1) of this section are also applicable for non-compliance by QHP issuers participating in State Exchanges and State-based Exchanges on the Federal platform when HHS is responsible for enforcement of the requirements in subpart E of this part and 45 CFR 156.50.

* * * * *

38. Section 156.805 is amended by—

- a. Revising paragraphs (a) introductory text and (a)(5)(i); and
- b. Adding paragraph (f).

The revisions and addition read as follows:

§ 156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

(a) *Grounds for imposing civil money penalties.* Civil money penalties may be imposed on an issuer in an Exchange if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

* * * *

(5) * *

(i) To HHS or an Exchange; or

* * * *

(f) *Circumstances requiring HHS enforcement in State Exchanges and State-based Exchanges on the Federal platform.* (1) HHS will enforce the requirements of subpart E of this part and 45 CFR 156.50 if a State Exchange or State-based Exchange on the Federal platform notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, *et seq.* that a State Exchange or State-based Exchange on the Federal platform is failing to substantially enforce these requirements.

(2) If HHS is responsible under paragraph (f)(1) of this section for enforcement of the requirements set forth in subpart E of this part or 45 CFR 156.50, HHS may impose civil money penalties on an issuer in a State Exchange or State-based Exchange on the Federal platform, in accordance with the bases and process for imposing civil money penalties set forth in this section.

Subpart J - Administrative Review of QHP Issuer Sanctions

39. Amend Subpart J by revising the heading to read as set forth above.

40. Section 156.901 is amended by revising the definitions of “Filing date” and “Hearing” to read as follows.

§ 156.901 Definitions.

* * * *

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

* * * * *

41. Section 156.903 is amended by revising paragraph (a) as follows:

§ 156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty of a QHP offered in a Federally-facilitated Exchange, State Exchange, and State-based Exchange on the Federal platform, or the decertification of a QHP offered in a Federally-facilitated Exchange.

* * * * *

42. Section 156.919 is amended by revising paragraph (a) to read as follows:

§ 156.919 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

* * * * *

43. Section 156.927 is amended by revising paragraphs (a) introductory text and (b) to read as follows:

§ 156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

44. Section 156.931 is revised to read as follows:

§ 156.931 Acknowledgement of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

45. Section 156.941 is amended by revising paragraph (e) to read as follows:

§ 156.941 Prehearing conferences.

* * * * *

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

* * * * *

46. Section 156.947 is amended by revising paragraph (a) to read as follows:

§ 156.947 The record.

(a) Any testimony that is taken in-person, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

* * * * *

47. Section 156.1210 is amended by--

- a. Revising paragraph (a);
- b. Redesignating paragraph (b) as paragraph (d); and
- c. Adding new paragraphs (b) and (c).

The additions read as follows:

§ 156.1210 Dispute submission.

(a) *Responses to reports.* Within 90 calendar days of the date of a payment and collections report from HHS, the issuer must, in a form and manner specified by HHS or the State Exchange describe to HHS or the State Exchange (as applicable) any inaccuracies it identifies in the report.

(b) *Inaccuracies identified after 90-day period.* With respect to an inaccuracy described under paragraph (a) of this section that is identified and submitted to HHS or the State Exchange (as applicable) by the issuer after the end of the 90-day period described in such paragraph, HHS will consider and work with the issuer or the State Exchange (as applicable) to resolve the inaccuracy so long as—

(1) The issuer promptly notifies HHS or the State Exchange (as applicable) upon identifying the inaccuracy, but in no case later than 15 calendar days after identifying the inaccuracy; and

(2) The failure to identify the inaccuracy and submit it to HHS or the State Exchange (as applicable) in a timely manner was not unreasonable or due to the issuer's misconduct or negligence.

(c) *Deadline for describing inaccuracies.* To be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before the later of —

(1) The end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates; or

(2) The date by which HHS notifies issuers that the HHS audit process with respect to the plan year to which such inaccuracy relates has been completed.

(3) If a payment error is discovered after the timeframes set forth in paragraph (c)(1) and (2) of this section, the issuer must notify HHS, the State Exchange, or SBE-FP (as applicable) and repay any overpayments to HHS.

* * * * *

48. Section 156.1215 is amended by revising paragraph (b) to read as follows:

§ 156.1215 Payment and collections processes.

* * * * *

(b) *Netting of payments and charges for later years.* As part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federally-facilitated Exchange user fees, payment of State Exchanges utilizing the Federal platform user fees, and risk adjustment, reinsurance, and risk corridors payments and charges.

* * * * *

49. Section 156.1220 is amended by—

- a. Revising paragraphs (a)(1)(vii) and (a)(3)(ii);
- b. Redesignating paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively; and
- c. Adding new paragraph (a)(3)(iii).

The revision and addition reads as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(1) * * *

(vii) The findings of a second validation audit as a result of risk adjustment data validation (if applicable) with respect to risk adjustment data for the 2016 benefit year and beyond; or

* * * *

(3) * * *

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

(iii) For 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, within 30 calendar days of publication of the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers;

* * * *

PART 158 – ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

50. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg-18.

51. Section 158.103 is amended by adding the definition for “Prescription drug rebates and other price concessions” in alphabetical order to read as follows:

§ 158.103 Definitions.

* * * *

Prescription drug rebates and other price concessions means all remuneration received by or on behalf of an issuer, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the issuer, that decrease the costs of a prescription drug covered by the issuer, regardless from whom the remuneration is received (for

example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates and other price concessions include discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits to the extent the value of these items reduce costs for the issuer, and excluding bona fide service fees. Prescription drug rebates and other price concessions exclude any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

* * * * *

§ 158.221 [Amended]

52. Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] amend § 158.221 by removing paragraph (b)(8) and redesignating paragraph (b)(9) as paragraph (b)(8).

53. Section 158.240 is amended by adding paragraph (g) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(g) *Rebate prepayment and safe harbor.* An issuer may choose to pay a portion or all of its estimated rebate amount for a given MLR reporting year to enrollees in any form specified in § 158.241 prior to the rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and in advance of submitting the MLR report required in § 158.110 to the Secretary. Issuers that choose to prepay a portion or all of their rebates must do so for all eligible enrollees in a given state and market in a non-discriminatory manner, and consistently with State law or other

applicable state authority. If, after submitting the MLR report required in § 158.110, an issuer determines that its rebate prepayment amount in a given state and market is at least 95 percent, but less than 100 percent, of the total rebate amount owed for the applicable MLR reporting year to enrollees in that state and market, the issuer may, without penalty or late payment interest under paragraph (f) of this section, provide the remaining rebate amount to those enrollees no later than the rebate deadlines in §§ 158.240(e) and 158.241(a)(2) applicable to the following MLR reporting year. If the total rebate owed to an enrollee for the MLR reporting year is above the *de minimis* threshold established in § 158.243(a), the issuer cannot treat the remaining rebate owed to an enrollee after prepayment as *de minimis*, even if the remaining rebate is below the *de minimis* threshold.

54. Section 158.241 is amended by revising paragraph (a)(2) to read as follows:

§ 158.241 Form of rebate.

(a) * * *

(2) For each of the 2011, 2012, and 2013 MLR reporting years, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2014 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after September 30 following the MLR reporting year. If the amount of the rebate exceeds the premium due for October, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with rebates due for the 2020 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the monthly premium that is due no later than October 30 following the MLR reporting year. If the amount of the rebate exceeds the monthly premium,

then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

* * * * *

55. Subchapter E as added in final rule published on November 27, 2019 (84 FR 65524) and effective on January 1, 2021 is amended by adding part 184 to read as follows:

**PART 184 – PHARMACY BENEFIT MANAGER STANDARDS UNDER THE
AFFORDABLE CARE ACT**

Sec.

184.10 Basis and scope.

184.20 Definitions.

184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

Authority: 42 U.S.C. 1302, 1320b-23.

§ 184.10 Basis and scope.

(a) *Basis.* (1) This part implements section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title XI of the Social Security Act.

(2) [Reserved]

(b) *Scope.* This part establishes standards for Pharmacy Benefit Managers that administer prescription drug benefits for health insurance issuers that offer Qualified Health Plans with respect to the offering of such plans.

§ 184.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Health insurance issuer has the meaning given to the term in § 144.103 of this subtitle.

Plan year has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 156.20 of this subchapter.

§ 184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, any entity that provides pharmacy benefits management services on behalf of a qualified health plan (QHP) issuer must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding *bona fide* service fees) that the pharmacy benefits manager (PBM) negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) *Bona fide* service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(b) *Limitations on disclosure.* Information disclosed by a PBM under this section shall not be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A PBM that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of section 1927(b)(3)(C) of the Act.

Dated: April 27, 2021.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2021-09102 Filed: 4/30/2021 8:45 am; Publication Date: 5/5/2021]