

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146, 149, 155, 156 and 158

[CMS–9916–F]

RIN 0938–AT98

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans

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

ACTION: Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It also finalizes changes related to essential health benefits and will provide states with additional flexibility in the operation and establishment of Exchanges. The rule includes changes related to cost sharing for prescription drugs; notice requirements for excepted benefit health reimbursement arrangements offered by non-Federal governmental plan sponsors; Exchange eligibility and enrollment; exemptions from the requirement to maintain coverage; quality rating information display standards for Exchanges; and other related topics. This final rule also repeats regulations relating to the Early Retiree Reinsurance Program.

DATES: These regulations are effective July 13, 2020.

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SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
- II. Background
 - A. Legislative and Regulatory Overview
 - B. Stakeholder Consultation and Input
 - C. Structure of Final Rule
- III. Provisions of the Final Regulations and Analysis and Responses to Public Comments
 - A. Part 146—Requirements for the Group Health Insurance Market: Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors
 - B. Part 149—Requirements for the Early Retiree Reinsurance Program
 - 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
- IV. Collection of Information Requirements
 - A. Wage Estimates
 - B. ICRs Regarding Notice Requirement for Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors
 - C. ICRs Regarding Special Enrollment Periods
 - D. ICRs Regarding Quality Rating Information Display Standards for Plan Years Beginning on or After January 1, 2021
 - E. ICRs Regarding State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020
 - F. ICRs Regarding Termination of Coverage or Enrollment for Qualified Individuals
 - G. ICRs Regarding Medical Loss Ratio (MLR)
 - H. Summary of Annual Burden Estimate for Final Requirements
- V. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Impact Estimates of the Payment Notice Provisions and Accounting Table
 - D. Regulatory Alternatives Considered
 - E. Regulatory Flexibility Act
 - F. Unfunded Mandates
 - G. Federalism
 - H. Congressional Review Act
 - I. Reducing Regulation and Controlling Regulatory Costs

I. Executive Summary

American Health Benefit Exchanges, or “Exchanges,” are entities established under the Patient Protection and Affordable Care Act¹ (PPACA) through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (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 PPACA also established the risk adjustment program, which is intended to increase the workability of the PPACA regulatory changes in the individual and small group markets, both on and off Exchanges.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies with authorities and

¹ The PPACA (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the PPACA, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the “Patient Protection and Affordable Care Act” or “PPACA”.

responsibilities under the PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. In this final rule, we are, within the limitations of current law, finalizing provisions to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility.

In previous rulemakings, we established provisions and parameters to implement many PPACA requirements and programs. In this final rule, we are amending some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These changes are intended to provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs. The provisions will also provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability. In the proposed rule, we solicited comments on modifying the automatic re-enrollment process for enrollees who would be automatically re-enrolled with advance payments of the premium tax credit (APTC) that would cover the enrollee's entire premium. We also announced that, pending such future rulemaking, HHS will not take enforcement action against Exchanges that do not implement a random sampling methodology during plan years 2020 and 2021.

Risk adjustment continues to be a core program in the individual and small group markets both on and off Exchanges, and we are finalizing the proposals to recalibrate the risk adjustment models used in the state payment transfer formula of the HHS-operated risk adjustment methodology, among other updates. As a refinement to the risk adjustment program, we are finalizing changes intended to improve the reliability of risk adjustment data validation (RADV).

As we do every year in the HHS notice of benefit and payment parameters, we are finalizing the user fee rates for issuers offering plans through the Exchanges using the Federal platform. For the 2021 plan year, we are maintaining the Federally-facilitated

Exchange (FFE) and State-based Exchange on the Federal platform (SBE-FP) user fees at the current 2020 plan year rates, 3.0 and 2.5 percent of total monthly premiums, respectively, in order to preserve and ensure that the FFE has sufficient funding to cover the cost of all special benefits provided to FFE issuers during the 2021 plan year.

As we do every year, we are updating the maximum annual limitation on cost sharing for the 2021 benefit year, including those for cost-sharing reduction (CSR) plan variations. These updates, which are required by law, will raise the annual limit on cost sharing, thereby increasing cost sharing and out-of-pocket spending for consumers who have out-of-pocket spending close to the annual cost-sharing limit.

We are committed to promoting a consumer-driven health care system in which consumers are empowered to select and maintain health care coverage of their choosing. To this end, we provide information to QHP issuers on ways in which they can implement value-based insurance plan designs that would empower consumers to receive high value services at lower costs. These value-based insurance plan designs will empower consumers and their providers to make evidence-based health decisions.

We also finalize new rules related to special enrollment periods. We will allow Exchange enrollees and their dependents who are enrolled in silver plans and become newly ineligible for CSRs to change to a QHP one metal level higher or lower, if they choose. We will require Exchanges to apply plan category limitations to dependents who are currently enrolled in Exchange coverage and whose non-dependent household member qualifies for a special enrollment period to newly enroll in coverage. We will also shorten the time between the date a consumer selects a plan through certain special enrollment periods and the effective date of that plan. In addition, we will allow all enrollees granted retroactive coverage through a special enrollment period the option to select a later effective date and pay for only prospective coverage. We also finalize the proposals to allow individuals and their dependents who are provided a qualified small employer health reimbursement arrangement (QSEHRA) on a non-calendar year basis to qualify for the existing special enrollment period for individuals enrolled in any non-calendar year group health plan or individual health insurance coverage. We will also allow enrollees whose requests for termination of their coverage were not implemented due to

an Exchange technical error to terminate their coverage retroactive to the date they attempted the termination, at the option of the Exchange.

To increase transparency in terminations of Exchange coverage or enrollment, we will require termination notices be provided in all scenarios where Exchange coverage or enrollment is terminated. We also will require excepted benefit health reimbursement arrangements (HRAs) sponsored by non-Federal governmental entities to provide a notice to participants that contains specified information about the benefits available under the excepted benefit HRA.

In addition, we are finalizing changes to the quality rating information display requirements for Exchanges. To continue providing flexibility for State Exchanges, we are codifying in regulation the option for State Exchanges that operate their own eligibility and enrollment platforms to display the quality rating information provided by HHS or to display quality rating information based upon certain state-specific customizations of the quality rating information provided by HHS.

Stable and affordable Exchanges with healthy risk pools are necessary for ensuring consumers maintain stable access to health insurance options. We are sharing our future plans for rulemaking to allow Exchanges to conduct 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. In order to make it easier for issuers to offer wellness incentives to enrollees and promote a healthier risk pool, we are finalizing the proposal that explicitly allows issuers to include certain wellness incentives as quality improvement activities (QIA) in the individual market for MLR reporting and calculation purposes.

We are also finalizing annual state reporting of state-required benefits that are in addition to essential health benefits (EHB), for which states are required to defray the costs. This will help to ensure that federal APTC dollars are protected and states are appropriately compensating enrollees or issuers for services that are in addition to EHB.

We are finalizing changes to the policy regarding whether drug manufacturer coupons must be applied towards the annual limitation on cost sharing. Specifically, we are revising § 156.130(h) to state that, to the extent consistent with applicable state law, amounts paid toward reducing the cost

sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing. However, we are not finalizing any change to the definition of cost sharing.

We are finalizing additional steps to ensure the proper execution of PPACA requirements and to safeguard and conserve federal funds. To protect against unnecessary overpayments of APTC funds, we will streamline the process for terminating coverage of enrollees who die while enrolled in Exchange coverage. In order to ensure that MLR reporting and rebate calculations are accurate, we are finalizing the proposal that issuers must report expenses for functions outsourced to or services provided by other entities consistently with issuers' non-outsourced expenses, and require issuers to deduct prescription drug rebates and price concessions from MLR incurred claims, not only when such rebates and price concessions are received by the issuer, but also when they are received and retained by an entity that provides pharmacy benefit management services to the issuer. Further, we are finalizing that where enrollees provide consent for the Exchange to end their QHP coverage if they are found to be dually enrolled in other qualifying coverage during the Exchange's periodic data matching (PDM) process, the Exchange will not be required to redetermine the enrollee's eligibility for financial assistance and may discontinue coverage consistent with the consent given by the enrollee.

Finally, we are repealing regulations currently set forth at 45 CFR part 149, governing the Early Retiree Reinsurance Program (ERRP) program and its implementation. The program sunset by law as of January 1, 2014.

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

“group health plan” includes both insured and self-insured group health plans.²

Section 1301(a)(1)(B) of the PPACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the PPACA, including coverage of the services described in section 1302(b) of the PPACA, adherence to the cost-sharing limits described in section 1302(c) of the PPACA, and meeting the actuarial value (AV) levels established in section 1302(d) of the PPACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost-sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the PPACA.

Section 1302 of the PPACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary), cost-sharing limits, and the levels of coverage for plans subject to the EHB requirements, according to their AV. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. Section 1302(d) of the PPACA describes the various levels of coverage based on their AV. Consistent with section 1302(d)(2)(A) of the PPACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the PPACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(c) of the PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section

1311(e)(1) of the PPACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the PPACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state. Section 1311(c)(6)(C) of the PPACA establishes special enrollment periods and section 1311(c)(6)(D) of the PPACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.³

Section 1311(c)(3) of the PPACA provides the Secretary with authority to develop a system to rate QHPs offered through an Exchange, based on relative quality and price. Section 1311(c)(4) of the PPACA authorizes 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 more than 500 enrollees in the prior year. Further, sections 1311(c)(3) and 1311(c)(4) of the PPACA require an Exchange to provide this quality rating information⁴ to individuals and employers on the Exchange's website.

Section 1311(d)(3)(B) of the PPACA permits a state, at its option, to require QHPs to cover benefits in addition to the EHB. This section also requires a state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional state-required benefits.

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

Sections 1313 and 1321 of the PPACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-

³ 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 Patient Protection and Affordable Care Act.

⁴ The term “quality rating information” includes the Quality Rating System (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”).

² 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 PPACA. The term “health plan” does not include self-insured group health plans.

discriminatory administration of State Exchange activities. Section 1321 of the PPACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the PPACA. Section 1321(a)(1) of the PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the PPACA for, among other things, the establishment and operation of Exchanges. When operating an FFE under section 1321(c)(1) of the PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the PPACA to collect and spend user fees and to allocate and manage those funds in order to support Exchange operations. Office of Management and Budget (OMB) Circular No. 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(d) of the PPACA provides that nothing in title I of the PPACA must be construed to preempt any state law that does not prevent the application of title I of the PPACA. Section 1311(k) of the PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

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

Section 1402 of the PPACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

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

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

Section 1411(f) of the PPACA requires the Secretary, in consultation with the Treasury and Homeland Security Department Secretaries 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 PPACA 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 PPACA allows the exchange 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.

Sections 2722 and 2763 of the PHS Act provide that the requirements of title XXVII of the PHS Act generally do not apply to excepted benefits. Excepted benefits are described in section 2791 of the PHS Act. This provision establishes four categories of excepted benefits. One such category is limited excepted benefits, which may include limited scope vision or dental benefits, and benefits for long-term care, nursing home care, home health care, or community based care. Section 2791(c)(2)(C) of the PHS Act, section 733(c)(2)(C) of the Employee Retirement Income Security Act (ERISA), and section 9832(c)(2)(C) of the Internal Revenue Code (the Code) authorize the Secretary of Health and Human Services, with the Secretaries of Labor and the Treasury (collectively, the Secretaries), to issue regulations establishing other, similar limited benefits as excepted benefits. To be excepted under the category of limited excepted benefits, section 2722(c)(1) of the PHS Act provides that limited benefits must either: (1) Be provided under a separate policy, certificate, or contract of insurance; or (2) otherwise not be an integral part of the plan.

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

Section 5000A of the Code, as added by section 1501(b) of the PPACA requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to \$0, effective for months beginning after December 31, 2018.⁵ Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under § 155.305(h).

1. Premium Stabilization Programs⁶

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409). In the June 19, 2013 **Federal Register** (78 FR 37032), we proposed a modification to the HHS-operated methodology related to community rating states. In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the proposed modification to the HHS-operated methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 **Federal Register** (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

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

⁵ Public Law 115–97, 131 Stat. 2054 (2017).

⁶ The term “premium stabilization programs” refers to the risk adjustment, risk corridors, and reinsurance programs established by the PPACA. See 42 U.S.C. 18061, 18062, and 18063.

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 FY 2015 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 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 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.⁷

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and in the March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). This final rule 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 as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.⁸

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

⁷ “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>.

⁸ “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>.

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 RADV audits. We published the 2020 Payment Notice final rule in the April 25, 2019, **Federal Register** (84 FR 17454).

On December 6, 2019, we published the HHS Risk Adjustment Data Validation (HHS–RADV) White Paper (2019 RADV White Paper).⁹

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 November 9, 2018 **Federal Register** (83 FR 56015), we published a proposed rule that proposed to amend standards relating to oversight of Exchanges established by states, periodic data matching frequency and authority, the length of a consumer’s authorization for the Exchange to obtain updated tax information, and requirements for certain issuers related to the collection of a separate payment for the premium portion attributable to coverage for certain abortion services. Many of the provisions in the proposed rule were finalized (2019 Program Integrity rule) in the December 27, 2019 **Federal Register** (84 FR 71674).

3. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 **Federal Register** (62 FR 16894). A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and beyond was published in the

⁹ The 2019 RADV White Paper is available at <https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper>.

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.

4. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and 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 an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058). In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83

FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period.

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin¹⁰ 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.

6. Cost-Sharing Requirements

In the 2020 Payment Notice, published in the April 25, 2019 **Federal Register** (84 FR 17454), we added § 156.130(h)(1) to clarify that issuers are not required to count toward the annual limitation on cost sharing any forms of direct support offered by drug manufacturers to reduce out-of-pocket costs for brand drugs when a generic drug is available and medically appropriate.

7. Excepted Benefit Health Reimbursement Arrangements

In the October 29, 2018 **Federal Register** (83 FR 54420), the Departments of Health and Human Services, Labor, and the Treasury (the Departments) published proposed regulations on HRAs and other account-based group health plans, including a new excepted benefit referred to as an excepted benefit HRA. In the June 20, 2019 **Federal Register** (84 FR 28888), the Departments published final regulations on HRAs and other account-based group health plans, including excepted benefit HRAs (the HRA rule).

8. 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 in the December 1, 2010 **Federal Register** (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), and the April 17, 2018 **Federal Register** (83 FR 16930).

9. Early Retiree Reinsurance Program (ERRP)

In the May 5, 2010 **Federal Register** (75 FR 24450), we published an interim final rule with comment period governing the ERRP. In the April 5, 2011 **Federal Register** (76 FR 18766), we published a notice informing the public that as of May 5, 2011, the ERRP would stop accepting applications for new participants in the program due to the availability of funds. In the December 13, 2011 **Federal Register** (76 FR 77537), we published a notice informing the public that, due to the availability of funds, the ERRP would deny reimbursement requests that include claims incurred after December 31, 2011. In the March 21, 2012 **Federal Register** (77 FR 16551), we published a notice establishing a timeframe within which plan sponsors participating in the program were expected to use ERRP reimbursement funds. Specifically, the notice informed participating plan sponsors that reimbursement funds should be used as early as possible, but not later than January 1, 2014.

10. Quality Rating System (QRS) and Enrollee Satisfaction Survey

Sections 1311(c)(3) of the PPACA directs the Secretary of HHS to develop a quality rating for each QHP offered through an Exchange, based on relative quality and price. Further, section 1311(c)(4) of the PPACA requires the Secretary to establish an enrollee satisfaction survey that evaluates the level of enrollee satisfaction of members with QHPs offered through the Exchanges for each QHP with more than 500 enrollees in the prior year. Exchanges are also required to make quality rating and enrollee satisfaction information available to individuals and

¹⁰ "Essential Health Benefits Bulletin." December 16, 2011. Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

employers on their respective websites. Consistent with these statutory provisions, in May 2014, HHS issued regulation at §§ 155.1400 and 155.1405 to establish the Quality Rating System (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.¹¹ 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.¹²

B. Stakeholder Consultation and Input

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

C. Structure of Final Rule

The regulations outlined in this final rule are codified in 45 CFR parts 146, 149, 153, 155, 156 and 158.

¹¹ Patient Protection and Affordable Care Act; 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 Quality Rating System (QRS) quality ratings and Qualified Health Plan (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>.

¹² See, for example, Center for Clinical Standards & Quality, CMS, The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2020 (October 2019), available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Quality-InitiativesGenInfo/Downloads/QRS-and-QHP-Enrollee-Survey-Technical-Guidance-for-2020-508.pdf>.

The changes to 45 CFR part 146 establish a notice requirement for non-Federal governmental plan sponsors that offer an excepted benefit HRA.

The changes to 45 CFR part 149 will delete the regulations related to the ERRP, which ended on January 1, 2014.

The provisions related to 45 CFR part 153 relate to recalibration of the risk adjustment models consistent with the approach outlined in the 2020 Payment Notice to transition away from the use of MarketScan® data and incorporate the most recent benefit years of enrollee-level EDGE data that are available for 2021 and beyond, as well as the ICD-10 HHS-HCC reclassification updates. The updates to the risk adjustment program also relate to the risk adjustment user fee for the 2020 benefit year, and modifications to RADV requirements for the states where HHS operates the risk adjustment program.

We are finalizing an amendment to the definitions applicable to 45 CFR part 155. We discuss future changes to part 155 that would allow Exchanges to implement a verification process for enrollment in or eligibility for an eligible employer-sponsored plan based on the Exchange's assessment of risk for inappropriate payments of APTC/CSR. We also clarify that an Exchange will not redetermine eligibility for APTC/CSRs for enrollees found to be dually enrolled in Medicare and QHP coverage who direct the Exchange to end their QHP coverage; clarify that when an Exchange identifies deceased enrollees via PDM, the Exchange will terminate coverage retroactively to the date of death; allow enrollees and their dependents eligible for a special enrollment period due to becoming newly ineligible for CSRs and are enrolled in a silver-level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment through an Exchange; establish that an Exchange must apply plan category limitations to currently enrolled dependents whose non-dependent household member qualifies for a special enrollment period to newly enroll the non-dependent household member in Exchange coverage; provide that in the FFE, special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection; align retroactive effective date and binder payment rules; establish that qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year would qualify for the existing special enrollment period for individuals enrolled in any non-calendar year group health plan or

individual health insurance coverage; and allow enrollees blocked from termination due to an Exchange technical error to terminate their coverage retroactive to the date they attempted the termination.

As we do every year in the HHS notice of benefit and payment parameters, we are updating the required contribution percentage, the maximum annual limitation on cost sharing, and the reduced maximum annual limitation on cost sharing based on the premium adjustment percentage. We are maintaining the FFE and SBE-FP user fees at the current 2020 plan year rates, 3.0 and 2.5 percent of total monthly premiums, respectively, to preserve and ensure that the FFE has sufficient funding to cover the cost of all special benefits provided to FFE and SBE-FP QHP issuers during the 2021 plan year. Further, we are finalizing a change to 45 CFR part 156 to require QHP issuers to send to enrollees a termination notice for all termination events. We also are amending the regulation addressing state selection of EHB-benchmark plans to require the reporting of state-required benefits. We also offer QHP issuers the option to design value-based insurance plans that would empower consumers to receive high value services at lower cost. We are revising § 156.130(h) in its entirety to address how any direct support offered by drug manufacturers to enrollees for specific prescription drugs may be treated with regard to accrual towards the annual limitation on cost sharing.

The changes to 45 CFR part 158 require issuers, for MLR purposes, to report expenses for functions outsourced to or services provided by other entities consistently with issuers' non-outsourced expenses, and to deduct from incurred claims prescription drug rebates and other price concessions received and retained by the issuer and other entities providing pharmacy benefit management services to the issuers. The changes to the MLR regulations would also explicitly allow issuers to report certain wellness incentives as QIA in the individual market.

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

In the February 6, 2020 **Federal Register** (85 FR 7088), we published the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans" proposed rule (proposed 2021 Payment Notice or proposed rule). We received 1,082

comments. 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.

Response: The timeline for publication of this final rule accommodates issuer filing deadlines for the 2021 plan year. A longer comment period would have delayed the publication of this final rule and created significant challenges for states, Exchanges, issuers, and other entities operating under strict deadlines related to approval of products.

Comment: Multiple commenters criticized the timing of the release of the proposed rule, stating that publishing the proposal for this annual rule in February 2020 creates challenges for states, Exchanges, issuers, and other entities in implementing changes for plan year 2021.

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

A. Part 146—Requirements for the Group Health Insurance Market: Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors

We proposed to add a new paragraph (b)(3)(viii)(E) to § 146.145 to establish notice requirements for excepted benefit HRAs offered by non-Federal governmental plan sponsors. We are

finalizing the notice requirements as proposed, except that we are modifying the applicability date so the new notice requirement applies to excepted benefit HRAs offered by non-Federal governmental plan sponsors for plan years beginning on or after 180 days following the effective date of the final rule.

Excepted benefit HRAs are a new type of excepted benefit the Departments recently established in the HRA rule.¹³ As proposed, the new paragraph would require sponsors of non-Federal governmental plans that offer excepted benefit HRAs to provide a notice to eligible participants that contains specified information about the benefits available under the excepted benefit HRA.

In the preamble to the HRA rule, the Departments noted that longstanding notice requirements under Part 1 of ERISA already apply to private-sector, employment-based plans. The Departments explained that under those notice requirements, excepted benefit HRAs that are subject to ERISA generally should provide information on eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the plan, and a description or summary of the benefits. Accordingly, the HRA rule included a cross-reference to existing ERISA notice provisions for excepted benefit HRAs that are subject to ERISA, to help ensure that sponsors of such excepted benefit HRAs are aware of their obligations under those provisions. However, the HRA rule did not finalize any notice requirements in addition to those ERISA already imposes on ERISA-covered plans. It also did not subject plans that are not subject to ERISA, such as excepted benefit HRAs sponsored by non-Federal governmental employers, to similar notice requirements.

We proposed to add new paragraph (b)(3)(viii)(E) to § 146.145 under which an excepted benefit HRA offered by a non-Federal governmental plan sponsor would be required to provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the excepted benefit HRA, and a description or summary of the benefits available under the excepted benefit HRA. We explained that this is generally consistent with the content requirements of Department of Labor (DOL) summary plan description regulations that apply to excepted benefit HRAs that are subject to ERISA at 29 CFR 2520.102–3(j)(2) and (3), although the proposed excepted benefit

HRA notice provided by a non-Federal governmental plan sponsor would be required to be provided annually and would not necessarily have to include every data element specified in those DOL regulations. We also proposed that the notice must be provided in a manner reasonably calculated to ensure actual receipt by participants eligible for the excepted benefit HRA, such as by providing the notice in the same manner in which the plan sponsor provides other notices or plan documents to plan participants.

Under existing DOL regulations at 29 CFR 2520.104b-2(a), ERISA-covered plans, including ERISA-covered excepted benefit HRAs, generally are required to furnish a copy of the notice to each participant no later than 90 days after the employee becomes a participant in the plan. Given that ERISA-covered plans and non-Federal governmental plans often contract with the same service providers to administer their health plans, to increase efficiencies and minimize costs and confusion, we proposed that the notice provided by non-Federal governmental excepted benefit HRAs must be provided no later than 90 days after the first day of the excepted benefit HRA plan year, or in the case of an employee who becomes a participant after the start of the plan year, no later than 90 days after the employee becomes a participant in the excepted benefit HRA.

We further proposed that the notice requirement would be applicable to excepted benefit HRA plan years beginning on or after 30 days following the effective date of the final rule.

We solicited comment on all aspects of the proposal, including whether to apply a different timing standard than the one proposed for the notices for non-Federal governmental excepted benefit HRAs, and any logistical, cost, and other challenges that would ensue from applying a different timing standard for the notice for such excepted benefit HRAs than for those regulated by ERISA. We also solicited comments on the proposed applicability date and on ways to mitigate the potential costs and burdens this notice requirement may impose on non-Federal governmental plan sponsors interested in offering excepted benefit HRAs. We also sought comment on whether sponsors of non-Federal governmental excepted benefit HRAs should be required to provide the notice annually after the initial notice, or whether, after providing the initial notice, they should only be required to provide the notice with respect to plan years for which the terms of the excepted benefit HRA change from the

¹³ 84 FR 28888 (June 20, 2019).

previous plan year, and if so, what type or magnitude of change should trigger such a subsequent notice.

We are finalizing the notice requirement as proposed, except for the applicability date, which we are extending based on comments received. This new notice requirement applies to excepted benefit HRAs offered by non-Federal governmental plan sponsors for plan years beginning on or after 180 days following the effective date of the final rule.

Comment: We received a relatively small number of comments regarding this proposal. Several commenters generally supported a notice requirement on excepted benefit HRAs sponsored by non-Federal governmental employers, without objecting to the proposed timing of the initial notice. Several commenters, while supporting the proposal generally, stated that contrary to the proposal, the notice should be provided *before* enrollment in the excepted benefit HRA, so consumers can make an informed decision about their coverage.

Response: We understand that many non-Federal governmental sponsors of excepted benefit HRAs may use the same third-party administrators as used by sponsors of excepted benefit HRAs that are subject to ERISA's timing requirements for excepted benefit HRA notices. In such cases, for administrative efficiency, non-Federal governmental sponsors of excepted benefit HRAs may prefer to send the notices to participants following their enrollment, within 90 days after they enroll in the excepted benefit HRA. Therefore, we are finalizing the notice timing standard as proposed. Furthermore, we agree that receiving the notices before enrollment may be useful for employees. Thus, we clarify that the timing standard in § 146.145(b)(3)(viii)(E) does not prohibit non-Federal governmental sponsors of excepted benefit HRAs from delivering the notice prior to enrollment. For example, a non-Federal governmental sponsor of an excepted benefit HRA may provide the notice on the 30th day before the start of the plan year and satisfy its obligation to provide the notice no later than 90 days after an employee becomes a participant. In this example, for employees who are not eligible for the excepted benefit HRA on the date the notice is otherwise provided, the notice must be provided no later than 90 days after the employee becomes a participant. We are not finalizing a limit on how early a non-Federal governmental plan sponsor may send the notice, but we encourage sponsors that opt to send the notice before the start of the excepted benefit

HRA plan year to send the notice in a timeframe that is reasonably calculated to ensure employees receive the notice at a time that would enable them to make an informed decision about their coverage.

Comment: One commenter supported the proposal that non-Federal governmental sponsors of excepted benefit HRAs be required to provide the notice annually. Another commenter recommended that a subsequent notice should be required only when there is a material change to the excepted benefit HRA from the previous plan year because without a material change, the subsequent notice would be unnecessary and unduly burdensome. Another commenter suggested that rather than require an annual notice, the regulations should track current ERISA requirements regarding subsequent notices, notices of material modifications of coverage, and notices of material reductions in covered services.

Response: We believe that an annual notice will benefit employees by ensuring that employees stay informed of their coverage options and helping employees understand how to utilize their excepted benefit HRA. Although we recognize that an annual notice may be somewhat more burdensome than if the notice were only required in certain circumstances in subsequent plan years, we do not believe the annual requirement will pose a significant burden on non-Federal governmental plan sponsors that would outweigh the benefit to employees. Further, to the extent there are no changes in the plan design, the burdens associated with development of the notice would be minimized for subsequent plan years. Therefore, we finalize the requirement that the notice be provided annually, as proposed.

Comment: One commenter stated that the notice requirement should be applicable for excepted benefit HRA plan years beginning on or after 1 year from the effective date of the final rule. The commenter asserted that understanding the scope of the notice requirements, identifying affected participants, developing the notice language, and delivering the notice would take more than 30 days.

Response: We do not agree that these tasks identified by the commenter are so complex as to justify delaying the proposed applicability date for 11 months. However, after considering comments received, in order to provide additional flexibility and time for non-Federal governmental plan sponsors to develop and send the notice, we are finalizing a later applicability date. As

finalized, the notice provision is applicable to excepted benefit HRAs offered by non-Federal governmental plan sponsors for plan years beginning on or after 180 days following the effective date of this final rule.

B. Part 149—Requirements for the Early Retiree Reinsurance Program (ERRP)

We proposed to delete part 149 of title 45 of the CFR, which sets forth requirements for participating in the ERRP, established by section 1102 of the PPACA. We will delete part 149 as proposed.

The ERRP provided financial assistance in the form of reinsurance to employment-based health plan sponsors—including for-profit companies, schools and educational institutions, unions, state and local governments, religious organizations, and other nonprofit plan sponsors—that made coverage available to early retirees, their spouses or surviving spouses, and dependents, for specified claims incurred prior to January 1, 2014, or until funding was depleted, whichever were to occur sooner. The goal of the program was to encourage and support comprehensive, quality health care for early retirees at least 55 years of age, and their spouses and dependents, not otherwise eligible for Medicare during the period preceding the effective date of the Exchanges and many of the market-wide rules created by the PPACA.

Under section 1102(a)(1) of the PPACA, the ERRP expired January 1, 2014. All ERRP payments have been made and there are no outstanding claims or disputes. A portion of the original appropriation remains, and will be returned to the Treasury when the appropriation is closed out in due course. Therefore, we proposed to delete the regulations in part 149 and reserve part 149 for future use, which would reduce the volume of Federal regulations.

We received no comments concerning the proposal. Therefore, we are repealing the regulations as proposed.

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

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2020,¹⁴ both the transitional reinsurance program and the permanent risk adjustment program are subject to the fiscal year

¹⁴ Available at https://www.whitehouse.gov/wp-content/uploads/2019/03/2020_JC_Sequestration_Report_3-18-19.pdf.

(FY) 2020 sequestration. The Federal Government's 2020 fiscal year began October 1, 2019. While the 2016 benefit year was the final year of the transitional reinsurance program, there could be reinsurance payments in FY 2020 for close-out activities. Therefore, the risk adjustment and reinsurance programs will be sequestered at a rate of 5.9 percent for payments made from FY 2020 resources (that is, funds collected during FY 2020).

HHS, in coordination with OMB, has determined that under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99-177, enacted December 12, 1985), as amended, and the underlying authority for the reinsurance and risk adjustment program, the funds that are sequestered in FY 2020 from the risk adjustment or reinsurance programs will become available for payment to issuers in FY 2021 without further Congressional action.

Additionally, in accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2021,¹⁵ the permanent risk adjustment program is subject to the FY 2021 sequestration. The Federal Government's 2021 fiscal year will begin October 1, 2020. Therefore, the risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from FY 2021 resources (that is, funds collected during FY 2021).

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99-177, enacted December 12, 1985), as amended, and the underlying authority for the risk adjustment program, the funds that are sequestered in FY 2021 from the risk adjustment program will become available for payment to issuers in FY 2022 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters for the Risk Adjustment Program

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by

section 1343 of the PPACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual and small group markets (including merged markets), inside and outside the Exchanges. In accordance with § 153.310(a), a state that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. HHS did not receive any requests from states to operate risk adjustment for the 2021 benefit year. Therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2021 benefit year.

Among other things, we proposed changes to recalibrate the risk adjustment models consistent with the methodology we finalized for the 2020 benefit year. For the 2021 benefit year, we proposed to incorporate the 3 most recent benefit years of enrollee-level EDGE data that are available, and to rely only on enrollee-level EDGE data for 2021 and beyond for purposes of recalibrating the HHS risk adjustment models. We also proposed the risk adjustment user fee for the 2021 benefit year, and modifications to certain RADV requirements.

a. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on age, sex, and diagnoses (grouped into hierarchical condition categories (HCCs)), producing a risk score. The current structure of these models is described in the 2020 Payment Notice.¹⁶ The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXC) beginning with the 2018 benefit year. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a 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 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.

(1) Updates to Data Used for Risk Adjustment Model Recalibration

We proposed to discontinue our reliance on MarketScan[®] data to recalibrate the risk adjustment models. Previously, we used the 3 most recent years of MarketScan[®] data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. For the 2019 benefit year, we recalibrated the models using 2 years of MarketScan[®] data (2014 and 2015) with 2016 enrollee-level EDGE data. The 2019 benefit year was the first recalibration year that enrollee-level EDGE data was used for this purpose. In keeping with our previously-stated intention to transition away from the MarketScan[®] commercial database, we further reduced our use of MarketScan[®] data in 2020 benefit year model recalibration by using only 1 year of MarketScan[®] data (2015), and the 2 most recent years of available enrollee-level EDGE data (2016 and 2017). During all 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.

Consistent with the policy announced in the 2020 Payment Notice,¹⁷ we proposed to no longer incorporate MarketScan[®] data in the recalibration process beginning with the 2021 benefit year. Rather, we proposed for the 2021 benefit year and beyond to blend the 3 most recent years of available enrollee-level EDGE data. Specifically, we proposed for the 2021 benefit year to blend the enrollee-level EDGE data from benefit years 2016, 2017, and 2018 to recalibrate the risk adjustment models. We also proposed to maintain the approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk

¹⁵ Available at https://www.whitehouse.gov/wp-content/uploads/2020/02/JC-sequestration_report_FY21_2-10-20.pdf.

¹⁶ See 84 FR 17454 at 17463.

¹⁷ 84 FR 17454 at 17464.

adjustment models for future benefit years beyond 2021, unless changed through rulemaking. We sought comment on these proposals.

After reviewing the public comments, we are finalizing our proposal to determine coefficients for the 2021 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. This approach will incorporate the most recent years' claims experience that is available while maintaining stability in risk scores, as the recalibration will maintain 2 years of EDGE data that were used in the previous years' models. It also will continue our efforts to recalibrate the risk adjustment models using data from issuers' individual and small group (including merged) market populations and complete the transition away from the MarketScan® commercial database that approximates individual and small group (including merged) market populations. Additionally, we are finalizing our proposal for future benefit years beyond 2021 to blend the 3 most recent years of available enrollee-level EDGE data.

Due to the timing of the proposed rule, we noted in the proposed rule that we were unable to incorporate the 2018 benefit year enrollee-level EDGE data in the calculation of the proposed coefficients in that rule. Therefore, consistent with the proposed 2017 and 2019 payment notices, the draft coefficients in the proposed rule were based on the 2 most recent years of data available at the time the proposed rule was drafted—the 2016 and 2017 benefit year enrollee-level EDGE data. Considering that 2 of the 3 years of enrollee-level EDGE data that we proposed to use to recalibrate the final 2021 risk adjustment models were reflected in the draft coefficients in the proposed rule, we explained that we believe that the draft coefficients listed in the proposed rule would provide a reasonably close approximation of what could be anticipated from blending the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. We noted in the proposed rule that if we finalize the proposed recalibration approach, but are unable to incorporate the 2018 benefit year EDGE data in time to publish the final coefficients in the final rule, we would publish the final coefficients for the 2021 benefit year in guidance after the publication of the final rule, consistent with our approach in previous benefit years.¹⁸ We were

unable to incorporate the 2018 benefit year EDGE data in time to publish the final coefficients in this final rule.

Therefore, consistent with § 153.320(b)(1)(i), we will release the final coefficients in guidance by June 2020 to allow for the incorporation in final rates for the 2021 benefit year.

We summarize and respond to public comments received on these proposals below.

Comment: Most commenters supported the proposal to determine coefficients for the 2021 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. Most commenters also supported maintaining the approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk adjustment models for future benefit years beyond 2021.

A few commenters expressed concern about when final blended coefficients for the risk adjustment models would be published. One commenter did not support HHS waiting until the release of the final payment notice to publish the final 2021 blended coefficients, and suggested HHS use coefficients developed from the 2 most recent years of available enrollee-level EDGE data, instead of the 3 most recent years, in order to provide two-year blended factors much earlier, perhaps even before the proposed rule. Another commenter also suggested HHS consider using only the 2 most recent years of data or, if using 3 years, weighting the most recent year more heavily given the lag in the data relative to how quickly changes in medical practice and technology impact the cost of care. Other commenters pointed out that issuers need the information on proposed coefficients for modeling and pricing much earlier than the timing of the proposed payment notice, especially given that many states require rate filings as early as May of the prior year. Another commenter requested confirmation that HHS will continue to publish the proposed coefficients in the proposed rule.

Response: We believe blending multiple years of data promotes stability and certainty for issuers in rate setting, helping to reduce year-to-year changes in risk scores and smooth significant differences in coefficients solved from any one year's dataset, particularly for conditions with small sample sizes. We also believe using the latest data available, especially with new drugs and technology coming to market, is the

best approach to improve overall model accuracy.

As we explained when finalizing the amendments to § 153.320(b)(1)(i), due to the fact that some data used to finalize coefficients may not be available until after publication of the applicable benefit year's final payment notice, we may not be able to provide finalized coefficients in the payment notice rulemaking.¹⁹ Instead, in these circumstances, we adopted an approach to release draft coefficients based on the 2 most recent years of data available, identify the datasets that would be used to calculate the final coefficients, and incorporate the additional, more recently available year's data in the final coefficients in subsequent guidance. This approach was followed in 2017 and 2019, and will also be followed for the 2021 benefit year.

We anticipate publishing the final coefficients for the 2021 benefit year by June 2020, which is prior to the deadline for final rate submissions,²⁰ to provide issuers with an opportunity to update their rate submissions, if necessary. In determining which data years to use, we seek to balance stability in risk scores year-over-year with the desire to incorporate the most recent data available on enrollees' risk. As some commenters noted, incorporating the most recent available year's data allows the risk adjustment models to reflect any changes in medical practice and technology (including newer or cheaper treatments). Particularly given recent rapid changes in treatment costs, we continue to believe incorporating the most recent years of data available more accurately reflects enrollees' risk. Using three years of data allows stability in model factors from the two prior benefit years' recalibration. However, in response to comments, we intend to consider whether overweighing the factors solved from the most recent data year available is warranted for future benefit years, as well as assess using factors solved from only 2 years of enrollee-level EDGE data available at the time of the proposed rule for future benefit years.

We also recognize the comments about the impact of delaying publication of blended coefficients and the comments requesting the final coefficients be made available by the time of initial state rate filing submissions. We will continue to look for opportunities to update our processes to provide draft and final

¹⁹ See 81 FR at 94084–94085.

²⁰ See, for example, <https://www.cms.gov/files/document/2020-final-rate-review-timeline-bulletin.pdf>.

¹⁸ For example, see the HHS Notice of Benefit and Payment Parameters for 2018 Final Rule (the 2018

Payment Notice), 81 FR 94058 (December 22, 2016). Also see 45 CFR 153.320(b)(1)(i).

recalibrated coefficients earlier, but we did not propose and are not making changes to the current schedule or approach for publication of the recalibrated coefficients at this time.

Comment: Commenters agreed that exclusively using enrollee-level EDGE data to recalibrate the HHS risk adjustment models better reflects the risk in the individual and small group (including merged) markets. One commenter encouraged HHS to continuously monitor and analyze potential long-term impacts of using enrollee-level EDGE data. Another commenter asked HHS to provide additional information about its blending methodology, including whether HHS adjusts the coefficients for expected one-time price hikes that would occur in the benefit year and not the data experience year or vice versa (for example, patent protection on brand drugs, or drugs losing a patent).

Response: We agree with commenters that exclusively using enrollee-level EDGE data to recalibrate the risk adjustment models will more closely reflect the relative risk differences of individuals in the individual and small group (including merged) markets compared to MarketScan® data, which generally reflects the large group market and was used in past years before enrollee-level EDGE data was available to approximate the HHS risk adjustment covered population.

As with every recalibration year, we continue to monitor the year-to-year changes in risk scores related to the data used, and will continue to monitor the potential long-term impacts of exclusively using enrollee-level EDGE data. HHS trends expenditures in each year's data to the applicable benefit year. Beginning with the 2017 benefit year, we trended medical services, preventive services, traditional (including brand and generic) prescription drug and specialty prescription drug expenditures separately based on varying growth rates observed in data available, in consultation with actuaries and industry reports.²¹ Except for the Hepatitis C drug pricing adjustment, discussed below, we do not currently adjust the model coefficients for one-time price changes that could occur in the benefit year.

To further explain our blending methodology, the coefficients are

²¹ For further details on trending, see the 2017 Payment Notice final rule (81 FR 12204 at 12218), and also the March 31, 2016 HHS Risk Adjustment Models White Paper, available at <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf>.

separately solved from each of the three years of data used in recalibration with applicable trend factors to account for anticipated cost changes between the data year and the applicable risk adjustment benefit year. The final blended coefficients for the applicable benefit year are created by averaging the separately solved coefficients across each of the three data years. The blending methodology is an average of three years' separately solved factors for each of the models, with each of the data years' factors equally weighted in the average as one-third of the final blended coefficients.²²

(2) Updates to Risk Adjustment Model Recalibration

i. Payment Hierarchical Condition Categories (HCCs)

The HHS–HCC clinical classification is the foundation of the models used in calculating transfers under the state payment transfer formula in the HHS–operated risk adjustment program established under section 1343 of the PPACA. Except for annual diagnosis code updates and the reconfiguration of one HCC,²³ the HHS–HCC clinical classification in terms of diagnosis code mappings has not been modified since it was implemented in the 2014 benefit year.

In preparation for proposing the changes in the proposed rule, we released a paper on June 17, 2019 entitled “Potential Updates to the HHS–HCCs for the HHS–operated Risk Adjustment Program” (HHS–HCC Updates Paper).²⁴ This paper described our methodology for reviewing and restructuring the HHS–HCC classification to incorporate ICD–10 diagnosis codes, and our intention to evaluate potential changes to the HHS–HCC model classification using enrollee-level EDGE data, which is representative of the population for which the models are targeted. Our main goal for reclassifying HHS–HCCs is to use them to update the HHS–HCC

²² For further details on blending, see the 2016 Payment Notice (80 FR 10760), and also the March 31, 2016 HHS Risk Adjustment Models White Paper, available at <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf>.

²³ As detailed in the 2018 Payment Notice, beginning with the 2018 benefit year, HCC 37 Chronic Hepatitis was split into two HCCs to distinguish the treatment costs of chronic hepatitis C: HCC 37_1 Chronic Viral Hepatitis C and HCC 37_2 Chronic Hepatitis, Except Chronic Viral Hepatitis C. See 81 FR 94058 at 94085 (December 22, 2016).

²⁴ The Potential Updates to HHS–HCCs for the HHS–operated Risk Adjustment Program (June 17, 2019) paper is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf>.

models to better incorporate coding changes made in the transition to the ICD–10 diagnosis classification system. We also used this opportunity to review and use the newly available 2016 and 2017 benefit years' enrollee-level EDGE claims data, which reflect the first 2 full years of ICD–10 diagnosis coding on claims. While this analysis did not consider updates to the RXCs,²⁵ it examined other components of the clinical classification, including payment and non-payment HCCs, certain clinical hierarchies, HCC groups and *a priori* constraints on HCC coefficients, and other HCC interactions affected by potential changes.

In the HHS–HCC Updates Paper, we explained our considerations for examining potential changes to HCCs and in determining which diagnosis codes should be included, how they should be grouped, and how the diagnostic groupings should interact for risk adjustment purposes, which is a critical step in the development of the HHS–HCC risk adjustment models. To guide the reclassification process, we used 10 principles that were discussed in the proposed 2014 Payment Notice that guided the creation of the original HHS–HCC diagnostic classification system,²⁶ and that were used to develop the HCC classification system for the Medicare risk adjustment model.²⁷ These principles included:

- *Principle 1*—Diagnostic categories should be clinically meaningful.
- *Principle 2*—Diagnostic categories should predict medical (including drug) expenditures.
- *Principle 3*—Diagnostic categories that will affect payments should have adequate sample sizes to permit accurate and stable estimates of expenditures.
- *Principle 4*—In creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each disease process, while the effects of unrelated disease processes accumulate.
- *Principle 5*—The diagnostic classification should encourage specific coding.

²⁵ RXCs were not implemented in the HHS–operated risk adjustment models until the 2018 benefit year and they currently only apply to the adult models.

²⁶ See the HHS Notice of Benefit and Payment Parameters for 2014, Proposed Rule, 77 FR 73118 at 73128 (December 7, 2012).

²⁷ Report to Congress: Risk Adjustment in Medicare Advantage (December 2018) also discusses these principles in Section 2.3 under “Principle for Risk Adjustment Models” from pages 14–16 and is available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf>.

- *Principle 6*—The diagnostic classification should not reward coding proliferation.

- *Principle 7*—Providers should not be penalized for recording additional diagnoses (monotonicity).

- *Principle 8*—The classification system should be internally consistent (transitive).

- *Principle 9*—The diagnostic classification should assign all diagnosis codes (exhaustive classification).

- *Principle 10*—Discretionary diagnostic categories should be excluded from payment models.

Using these principles, we conducted a multi-step analysis of the current HHS–HCC classification to develop the list of HCC changes that we proposed.

We began by conducting a comprehensive review of the current HHS–HCC full classification and risk adjustment model classification, including an examination of disease groups with extensive ICD–10 code classification changes, HCCs whose counts had changed considerably following ICD–10 implementation, clinical areas of interest (for example, substance use disorders), and model under-prediction or over-prediction as identified by predictive ratios. We then examined HCC reconfigurations, payment HCC designation, HCC Groups, and hierarchies to develop the preliminary regression analyses using 2016 data.²⁸ We also conducted a series of clinical reviews to inform potential changes. Next, we reviewed the payment model and full classification regressions to compare frequencies and predicted incremental costs of HCCs. Then, we repeated the preliminary regression analyses using 2017 data, reviewed regression results, and developed the new potential HHS–HCC reclassification.²⁹

During our analysis, for some disease groups such as substance use disorders and pregnancy, we explored multiple model variations. For substance use disorders, we tested different configurations to add new drug use disorder HCCs and alcohol use disorder HCCs to the HHS–HCC risk adjustment

models—a single hierarchy approach; two hierarchies (drug and alcohol HCCs being additive); interaction terms; and for each of these iterations, grouping HCCs or leaving them ungrouped. For pregnancy, we tested different configurations for adding ongoing pregnancy HCCs to the model, which already includes miscarriage HCCs and completed pregnancy HCCs. These configurations included a single hierarchy or separate additive HCCs to distinguish pregnancy care from delivery; interactions between completed and ongoing pregnancy HCCs to account for when in the episode of care complications occur; and removal of or changes to HCC groups to better reflect cost distinctions. In evaluating options for reclassification, we considered their predictive power, model complexity, and coding incentives.

Based on this analysis, we proposed to incorporate the HCC changes identified in the HHS–HCC Updates Paper beginning with the 2021 benefit year risk adjustment models.³⁰ As discussed in the proposed rule, the main purpose of the proposed HCC changes is to update the HCCs based on availability of more recent diagnosis code information and the availability of more recent claims data. To provide risk adjustment factors that best reflect more recent treatment patterns and costs, we proposed to update the HHS–HCC clinical classification in the V05 HHS–HCC risk adjustment models by using more recent claims data to develop updated risk factors, as part of our continued assessment of modifications to the HHS-operated risk adjustment program for the individual, small group, and merged markets.

We proposed to apply all of the HHS–HCC changes at one time for the 2021 benefit year and beyond to account for all of the ICD–10 coding changes. Additionally, to assist commenters in reviewing the code level changes, we provided a crosswalk of ICD–10 codes to the proposed HCCs under the “Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year”, which is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html>.³¹ While we

recognized that the number of HHS–HCC changes we proposed was significantly higher than in previous annual notices of benefit and payment parameters, we noted in the proposed rule that we do not expect to make significant HHS–HCC changes each year. We solicited comment on all of the proposed HHS–HCC updates. Following our review of public comments, we are finalizing our proposal to update the HHS–HCC classifications to incorporate ICD–10 diagnosis codes with slight modifications to specific payment HCCs as outlined further below, referred to as the Version 07 (“V07”) classification.

Specifically, we carefully considered comments received regarding the HHS–HCC reclassifications and are finalizing certain modifications to our proposals in response. First, although we are finalizing our proposal to revise the current HCCs 81 (Drug Psychosis) and 82 (Drug Dependence) and add separate HCCs related to alcohol use (HCC 83 and 84), we are not finalizing our proposal to create a fifth HCC, HCC 85 (Drug Use Disorder, Mild, Uncomplicated, Except Cannabis), in the adult, child, or infant models. We agree with commenters that further review of HCC 85 is necessary, including within the context of RADV, prior to adding to that HCC.

As also recommended by commenters, we are finalizing the grouping of the two drug use disorders (revised HCCs 81 and 82 together) and the two alcohol use disorders (HCC 83 and 84 together) in the adult models, consistent with the approach proposed for the child models.

Because we proposed to update the hierarchy positions for mental health HCCs, we also proposed to switch the numbering for HCC 88 and HCC 89, while also renaming both HCCs. Commenters found the proposed number switches for these two HCCs in the child and adult models confusing; therefore, we are finalizing the proposed change in hierarchy position of these HCCs and the proposed renaming of both HCCs, but we are finalizing a modified numbering of these HCCs in V07 from those proposed in V06b as

for the 2021 Benefit Year reflects changes proposed in the 2021 Payment Notice proposed rule as referenced in this rule as “V06b.” This draft crosswalk included Table 3, which crosswalks ICD–10 codes to the Condition Categories (CCs) in the risk adjustment models, and Table 4, which provides the hierarchy rules to apply to the CCs to create HCCs. These Tables are similar to the Tables 3 and 4 that HHS includes as part of the HHS–Developed Risk Adjustment Model Algorithm “Do It Yourself (DIY)” Software. We expect to replace the draft crosswalk with an updated crosswalk based on the V07 changes being finalized in this rule in the future, and will make it available on our website as well.

²⁸ Payment HCCs are those included in the HHS–HCC risk adjustment models. The full classification includes both payment and non-payment HCCs. HCC Groups refers to payment HCCs that are grouped together in the HHS–HCC risk adjustment models.

²⁹ To further clarify, in the HHS–HCC Updates Paper, V05 reflects the current classification model, V06 is the initial assessment of potential revisions to the classification model developed using the 2016 benefit year data, and V06a is the reassessment of potential revisions to the classification model that included 2017 benefit year data. In this rule, V06b is the revised HCC changes in the proposed rule and V07 is the revised classification model being finalized.

³⁰ As explained in the proposed rule, we proposed one modification to the child models from the potential updates described in the HHS–HCC Updates Paper. We proposed and are finalizing below in this rule that the removal of a constraint for HCC 159 Cystic Fibrosis to allow it to have higher predicted costs than HCC 158 Lung Transplant Status/Complications.

³¹ The Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model

shown in Table 1. Specifically for V07, we are retaining the numbering, but renaming HCC 88 (Major Depressive Disorder, Severe, and Bipolar Disorders), renumbering and renaming

proposed HCC 89 (Reactive and Unspecified Psychosis, Delusional Disorders) as HCC 87.2 (Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis) because it

would place HCC 87.2 above HCC 88 in the hierarchy. To accommodate this change, we are also renumbering Schizophrenia from HCC 87 to HCC 87.1 to maintain its place in the hierarchy.

TABLE 1—MODIFIED V07 NUMBERING OF THESE HCCs FROM THOSE PROPOSED IN V06b

V05 HCC	V05 HCC label	V06b HCC	V06b HCC label	V07 HCC	V07 HCC label
87	Schizophrenia	87 88	Schizophrenia Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis.	87_1 87_2	Schizophrenia. Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis.
88	Major Depressive and Bipolar Disorders.	89	Major Depressive Disorder, Severe, and Bipolar Disorders.	88	Major Depressive Disorder, Severe, and Bipolar Disorders.
89	Reactive and Unspecified Psychosis, Delusional Disorders.				

In addition to the above modifications, and consistent with HHS’s commitment to continuously assess the HHS-operated risk adjustment program based on analysis of more recent available data and the objectives in the HHS–HCC Updates Paper, we further analyzed the HCC classifications using 2018 enrollee-level EDGE data once it was available. Based on this review, we determined the costs related to two HCCs in the infant models were better aligned with severity level four, rather than the proposed classification of severity level three.³² In addition, we identified two clinically-related HCCs in the child models that have small sample sizes. Therefore, consistent with the general policy that the models should avoid creating HCCs with low sample sizes and possibly unstable estimates, we will group them to improve the predictive power and stability of the child models. We also identified one new proposed HCC in the child model that has a sufficient sample size, and therefore, we will be not be grouping it, as proposed. Details on these changes to the infant and child models are described below. We note that these additional modifications relate to certain HCCs in the infant and child models to further improve the risk prediction and stability of the models. These shifts in placement do not change the number or type of HCCs included in the infant and child models beyond what was proposed. We believe that

each change described below, while small in effect, will improve risk prediction and ensure stability of the models. Therefore, we are finalizing the following additional HCC classification changes to the infant and child models:

- In the infant models, we are not finalizing the proposed move of HCC 73 (Combined and Other Severe Immunodeficiencies) from severity level four to severity level three; it will remain classified as severity level four. The costs for HCC 73 are better aligned with severity level four upon further review of an additional data year.
- In the infant models, we are also moving HCC 30 (Adrenal, Pituitary, and Other Significant Endocrine Disorders) from severity level three to level four. Upon review of an additional data year, we concluded that the costs for HCC 30 are better aligned with severity level four.
- In the child models, we are grouping HCC 131 (Acute Myocardial Infarction) and HCC 132 (Unstable Angina and Other Acute Ischemic Heart Disease) because our review of an additional data year identified small sample sizes for these HCCs.
- In the child models, we are finalizing, as proposed, the grouping of HCC 210 ((Ongoing) Pregnancy without Delivery with Major Complications) with HCC 211 ((Ongoing) Pregnancy without Delivery with Complications) due to the small sample sizes associated with these HCCs for this population. However, we are not finalizing the proposal to group these two HCCs with the proposed new HCC 212 ((Ongoing) Pregnancy without Delivery with No or Minor Complications). Upon review of the additional data year, we determined the sample size for HCC 212 in the child models is sufficient such that grouping it with HCC 210 and HCC 211 is not necessary.

Lastly, we are also finalizing one additional diagnosis coding update to the adult risk adjustment models in light of the finalized updates to the HCCs in this rulemaking. We are including the proposed HCC 35.1 (Acute Liver Failure/Disease, Including Neonatal Hepatitis) in the RXC–HCC interaction term for RXC 02 (Anti-Hepatitis C (HCV) Agents). RXC 02 (Anti-Hepatitis C (HCV) Agents) was previously paired with HCC 37.1 (Chronic Viral Hepatitis C), HCC 36 (Cirrhosis of Liver), HCC 35.2 (V05 HCC 35, End-Stage Liver Disease), and HCC 34 (Liver Transplant Status/Complications), listed in ascending order of position in the V05 hierarchy. Anti-Hepatitis C (HCV) Agents are primarily prescribed for HCC 37.1 (Chronic Viral Hepatitis C); however, because of clinical hierarchies, other HCCs that are clinically more severe than the HCC primarily associated with the RXC (HCC 37.1) are also included in the RXC–HCC interaction. In the proposed rule, HHS proposed to move HCC 38 (Acute Liver Failure/Disease Including Neonatal Hepatitis) above HCC 35 (End Stage Liver Disease) in the related HCC hierarchy to address cost implications of chronic versus acute liver failure. Due to the change in hierarchy positions, we proposed to renumber these HCCs to HCC 35.1 (Acute Liver Failure/Disease, Including Neonatal Hepatitis), and HCC 35.2 (Chronic Liver Failure/End Stage Liver Disorders), respectively. Because HCC 35.1 (Acute Liver Failure/Disease, Including Neonatal Hepatitis) was proposed and is being finalized in the hierarchy above the HCC most closely related to RXC 02 (Anti-Hepatitis C (HCV) Agents), HCC 37.1 (Chronic Viral Hepatitis C), we are adding HCC 35.1 to the RXC 02 interaction term as part of

³²The infant models use a categorical approach because infants (ages 0–1) have low frequencies for most HCCs, which leads to unstable parameter estimates in an additive model. Infants are assigned a birth maturity (by length of gestation and birth weight as designated by their newborn payment HCC) or age 1 category, and a disease severity category (based on HCCs other than birth maturity). There are five maturity categories and five disease severity categories (based on clinical severity and associated costs).

the updates finalized in this rulemaking. Therefore, in addition to finalizing the below revisions to the liver HCC hierarchy, we are also finalizing the addition of this HCC for the RXC 02 interaction term in the adult models.

In the proposed rule, we also proposed one modification to the child models from the potential updates described in the HHS–HCC Updates Paper. In the paper, we noted that we may re-examine the hierarchy violation constraints for non-transplant HCCs in the child models that affect the predicted costs of the transplant set. We explained that HCC 159 (Cystic Fibrosis) in the child models, which has high associated drug costs, has higher predicted costs than HCC 158 (Lung Transplant Status/Complications). For this reason, a hierarchy violation was occurring whereby the higher-cost HCC 159 (Cystic Fibrosis) was being constrained to the lower-cost transplant

coefficients. To improve cost prediction, we proposed to not impose a hierarchy violation constraint in the child models beginning with the 2021 benefit year coefficients for HCC 159 (Cystic Fibrosis), allowing it to have higher predicted costs than HCC 158 (Lung Transplant Status/Complications). We are finalizing this proposed change, and are also adding a similar change for parallel reasons. We also will not impose a hierarchy violation constraint in the child models beginning with the 2021 benefit year coefficients for HCC 35.1 (Acute Liver Failure Disease, Including Neonatal Hepatitis) and HCC 35.2 (Chronic Liver Failure/End-Stage Liver Disorders), allowing them to have higher predicted costs than the liver transplant HCC 35 (Liver Transplant Status/Complications). Thus, we are finalizing in V07 not to impose hierarchy violation constraints in the child models for two sets of non-

transplant HCCs that have higher associated costs than the transplant HCC above them in their hierarchy: (1) Liver failure HCC 35.1 (Acute Liver Failure Disease, Including Neonatal Hepatitis) and HCC 35.2 (Chronic Liver Failure/End-Stage Liver Disorders) and HCC 34 (Liver Transplant Status/Complications); and (2) HCC 159 (Cystic Fibrosis) and HCC 158 (Lung Transplant Status/Complications).

All of the final payment HCC changes for the 2021 benefit year risk adjustment models and beyond, including these additional modifications, are reflected in Table 2 and referred to as “V07” below. The HCC classification for the 2020 benefit year is referred to as “V05”, the classification changes discussed in the HHS–HCC Updates Paper are referred to as “V06a,” and the classification changes proposed in the 2021 Payment Notice proposed rule are referred to as “V06b.”

TABLE 2—SUMMARY OF FINAL PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES [V07]

Condition	Payment HCC final change	Summary of final payment HCC changes
Payment HCC Changes		
Substance Use Disorders	+2	<ul style="list-style-type: none"> • Add 2 new HCCs for alcohol use disorders for all models¹ to risk adjust for a larger number of substance use diagnoses. • Reconfigure drug dependence HCC to include drug use disorders with non-psychotic complications and a subset of drug poisoning (overdose) codes to reflect the revised conceptualization of substance use disorders in ICD–10. • Group the drug use HCCs (81 and 82) into one group and the alcohol use HCCs (83 and 84) in another group for adult and child models. • Impose a new combined hierarchy on drug use and alcohol use HCCs due to the high prevalence of both drugs and alcohol use among those with alcohol or drug use disorders.
Pregnancy	+3	<ul style="list-style-type: none"> • Add 3 (ongoing) pregnancy-without-delivery HCCs to child and adult models. Leave them ungrouped in the adult models to reflect differences in costs by level of complications. Group the two higher HCCs (210 and 211) in the child models to address small sample sizes and unstable estimates. • Revise two existing pregnancy HCC Groups in both adult and child models, separating out the ectopic/molar pregnancy HCC and the uncomplicated pregnancy-with-delivery HCC to better distinguish incremental costs.
Diabetes	+1	<ul style="list-style-type: none"> • Add a diabetes type 1 additive HCC to the adult models to distinguish additional costs for diabetes type 1. • Remap hyperglycemia and hypoglycemia codes from the “chronic complications” HCC to the “without complication” HCC based on clinical input.
Asthma	+1	<ul style="list-style-type: none"> • Split current asthma HCC into two severity-specific HCCs for all models given new clinical distinctions for severity levels in the ICD–10 and to distinguish costs by severity. • Continue to group asthma HCCs with chronic obstructive pulmonary disease HCC in adult models and leave the 3 HCCs ungrouped to distinguish costs in child models.
Fractures	–1, +1	<ul style="list-style-type: none"> • Delete an HCC (pathological fractures) for all models to address a clinical distinction that may be inconsistently diagnosed/coded. • Reconfigure an existing HCC (hip fractures) to better distinguish fracture codes by site. • Add a new HCC (vertebral fractures) for all models to better predict vertebral fractures, which may be indicative of chronic disease and frailty.
Third Degree Burns and Major Skin Conditions	+2	<ul style="list-style-type: none"> • Reconfigure and add 2 HCCs (extensive third degree burns; major skin burns or conditions) for all models in an imposed hierarchy because these HCCs are currently being under-predicted, contain chronic conditions or are burns that involve long-term follow up care. • Impose an <i>a priori</i> constraint² between extensive third degree burns and severe head injury in child models due to small sample size.
Coma and Severe Head Injury	+1	<ul style="list-style-type: none"> • Add a new severe head injury HCC (represents a condition with ongoing care costs; similar to the inclusion of other injury HCCs) for all models in a hierarchy above the coma/brain compression HCC. • Impose an <i>a priori</i> constraint between extensive third degree burns and severe head injury in the child models due to small sample size.

TABLE 2—SUMMARY OF FINAL PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES—Continued
[V07]

Condition	Payment HCC final change	Summary of final payment HCC changes
Traumatic Amputations	+1	<ul style="list-style-type: none"> • Add a new HCC in a hierarchy with the current amputation status HCC for all models and reconfigure codes between the new HCC and current amputation status HCC to better distinguish early treatment and complication costs from long-term costs. • Leave HCCs ungrouped in the adult models; group them in the child models for coefficient stability purposes due to small sample size.
Narcolepsy and Cataplexy	+1	<ul style="list-style-type: none"> • Add a new HCC to both child and adult models because these conditions are currently under-predicted and have associated treatment costs.
Exudative Macular Degeneration	+1	<ul style="list-style-type: none"> • Add a new HCC to adult models because the condition is currently under-predicted; costs are primarily related to drug treatments.
Congenital Heart Anomalies	new to adult	<ul style="list-style-type: none"> • Add 3 new HCCs to adult models (already in the child and infant models) because the conditions are currently under-predicted. Group them in the adult models only.
Changes in HCC Groups, Hierarchies		
Metabolic and Endocrine Disorders	N/A	<ul style="list-style-type: none"> • Group HCCs 26 and 27 together in both the child and adult models to distinguish their significantly higher incremental costs from other HCCs (HCCs 28–30) previously in the full group (HCCs 26 and 27 are currently under-predicted in these models due to grouping). • Ungroup HCCs 29 and 30 in the adult models as they have adequate sample sizes and clinical and cost distinctions. • Group HCCs 28 and 29 in the child models due to small sample sizes, clinical similarity, and similar predicted costs. • Leave HCC 30 ungrouped in the child models because it is clinically distinct from HCCs 28 and 29.
Necrotizing Fasciitis	N/A	<ul style="list-style-type: none"> • Ungroup the necrotizing fasciitis HCC (HCC 54) in the adult models to better predict higher incremental costs compared to HCC 55 (the condition that is currently grouped with this HCC).
Blood Disorders	N/A	<ul style="list-style-type: none"> • Revise groups in both adult and child models to move HCC 69 from its previous grouping with HCCs 70 and 71 to the group with HCCs 67 and 68 to better reflect clinical severity and associated costs. • Reconfigure HCCs 69 and 71 based on clinical input.
Acute Myocardial Infarction and Unstable Angina ..	N/A	<ul style="list-style-type: none"> • Group HCCs 131 and 132 in the child models for coefficient stability purposes due to small sample size.
Mental Health	N/A	<ul style="list-style-type: none"> • Move delusional disorders/psychosis HCC above major depressive disorders/bipolar disorders HCC in the hierarchy (the HCCs switch position in the hierarchy) because the costs and diagnoses associated with the delusional disorders/psychosis HCC are more aligned with the schizophrenia HCC. Renumber the two highest HCCs in the hierarchy: HCC 87_1 Schizophrenia (had been 87) and HCC 87_2 Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis (had been 89). HCC 88 Major Depressive Disorder, Severe, and Bipolar Disorders retains its same number. • Relabel HCCs to align with ICD–10 categorizations.
Cerebral Palsy and Spina Bifida	N/A	<ul style="list-style-type: none"> • Refine hierarchies to exclude paralysis HCCs for enrollees with cerebral palsy HCCs, as ICD–10 coding guidelines prohibit these conditions from coding together. • Refine hierarchies to exclude hydrocephalus HCC for enrollees with spina bifida HCC for similar coding restriction purposes.
Pancreatitis	N/A	<ul style="list-style-type: none"> • Reconfigure the acute pancreatitis HCC to move pancreatic disorders and intestinal malabsorption out of the acute pancreatitis HCC to differentiate higher cost conditions. • Revise the hierarchy for pancreas transplant HCC to remove exclusion of pancreatitis HCCs because pancreas transplants are done primarily for diabetes and insulin conditions rather than pancreatitis.
Liver	N/A	<ul style="list-style-type: none"> • Reconfigure codes in liver HCCs to reflect clinical distinctions. • Move acute liver failure HCC above chronic liver failure HCC in the hierarchy and renumber HCCs to address cost implications of chronic versus acute liver failure.
Summary of the Adult Model Specific Changes		
Payment HCC change	+16	<ul style="list-style-type: none"> • Net change of 16 HCCs; 17 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Severe Illness Interactions	–1 (other model variable)	<ul style="list-style-type: none"> • Remove medium cost severe illness interaction term from model because its parameter estimate is usually very low or negative.
Summary of the Child Model Specific Changes		
Payment HCC change	+11	<ul style="list-style-type: none"> • Net change of 11 HCCs; 12 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Transplant <i>A Priori</i> Constraints	N/A	<ul style="list-style-type: none"> • Revise <i>a priori</i> constraints applied to the transplant HCCs to better distinguish costs while improving estimate stability due to small sample sizes. • Do not impose hierarchy violation constraints for two sets of non-transplant HCCs that have higher associated costs than the transplant HCC above them in their hierarchy: (1) Liver failure HCCs 35.1 and 35.2 and HCC 34 Liver Transplant Status/Complications; and (2) HCC 159 Cystic Fibrosis and HCC 158 Lung Transplant Status/Complications.

TABLE 2—SUMMARY OF FINAL PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES—Continued
[V07]

Condition	Payment HCC final change	Summary of final payment HCC changes
Summary of the Infant Model Specific Changes		
Payment HCC change	+7	<ul style="list-style-type: none"> • Net change of 7; 8 HCCs added and 1 HCC deleted (for details see the above portion of this table). • Revise severity level assignments of a subset of HCCs to better reflect clinical severity and costs and assign new HCCs to severity levels. • Reconfigure code assignments to newborn HCCs for subset of codes whose weeks gestation classification in ICD–10 differed from ICD–9.
Categorical Model	N/A	

¹ References to “all models” in Table 2 refers to the adult, child and infant models.

² In *a priori* constraints, the HCC estimates are constrained to be equal to each other. These are applied to stabilize high cost estimates that may vary greatly due to small sample size.

The following is a summary of the public comments we received on the proposed ICD–10 HHS–HCC reclassification updates to the HHS risk adjustment models.

Comment: Some commenters requested that HHS provide additional transparency about the data used in updating the HCCs, such as the alternatives we considered, the criteria used to develop our proposals and the impact of changes. Other comments requested that HHS demonstrate the contribution of each specific updated or modified HCC to the model and how it improves the accuracy of identifying risk selection compared to the existing model. Some commenters request that the HCC change be tested with the most recent year of EDGE data.

Response: We agree with commenters about the importance of transparency in developing and finalizing HCC updates. We refer commenters to the HHS–HCC Updates Paper, released on June 17, 2019, in which we provided a preview of the proposed changes with detailed estimated costs between the current classification and the proposed classification, as well as the impact of the changes on the adult, child and infant risk adjustment models. In the HHS–HCC Updates Paper and the proposed rule, we outlined the principles (or criteria) used to develop the proposed ICD–10 HHS–HCC reclassifications updates.³³ In both documents, we also explained the process we used to develop the proposed updates.

We began this process by conducting a comprehensive review of the current HHS–HCC full classification and risk adjustment model classification, including an examination of disease groups with extensive ICD–10 code classification changes, HCCs whose counts had changed considerably following ICD–10 implementation, clinical areas of interest (for example,

substance use disorders), and model under-prediction or over-prediction as identified by predictive ratios. We then examined HCC reconfigurations, payment HCC designation, HCC Groups, and hierarchies to develop the preliminary regression analyses using 2016 enrollee-level EDGE data.³⁴ We also conducted a series of clinical reviews to inform potential changes. Next, we reviewed the payment model and full classification regressions to compare frequencies and predicted incremental costs of HCCs. To validate our initial reclassifications, we repeated the preliminary regression analyses using 2017 enrollee-level EDGE data, as well as 2016 and 2017 MarketScan® data. Results of the initial and validation analyses informed the proposed HHS–HCC reclassifications in model V06a, which were based on 2016 and 2017 enrollee-level EDGE data. We analyzed proposed V06b HCCs on 2018 enrollee-level EDGE data once it became available.

In the HHS–HCC Updates Paper, we estimated that the impact of moving from V05 to V06a³⁵ would result in a slight improvement in model prediction and a slight increase in the number of

³⁴ Payment HCCs are those included in the HHS–HCC risk adjustment models. The full classification includes both payment and non-payment HCCs. HCC Groups refers to payment HCCs that are grouped together in the HHS–HCC risk adjustment model.

³⁵ To further clarify, in the HHS–HCC Updates Paper, V05 reflects the current classification model, V06 is the initial assessment of potential revisions to the classification model developed using the 2016 benefit year data, and V06a is the reassessment of potential revisions to the classification model that included 2017 benefit year data. V06b is the revised HCC changes in the proposed rule and V07 is the revisions to the classification model being finalized in this rule. The changes in the proposed rule (V06b) were reflected in the “Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year”, which is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html>. We expect to replace the draft crosswalk with an updated crosswalk based on the V07 changes being finalized in this rule in the future, and will make it available on our website as well.

enrollees with one or more payment HCCs in the adult and child models. Although some commenters requested data showing specifically how changes impact state-level transfers, we note that we do not extract state identifiers in the enrollee-level EDGE data, and therefore, we are unable to directly assess state level impacts. Instead, we evaluated impacts at the national level. Between the proposed and final rules, we conducted an additional analysis of our proposed V06b classifications and the resulting impact on average national enrollee risk scores. We estimated an increase in national enrollee risk scores of approximately one percent.³⁶

In addition to the HHS–HCC Updates Paper that was posted in June 2019, we released a crosswalk alongside the proposed rule to allow issuers to assess the impact of the proposed changes on the risk scores for their plans or enrollees. Commenters did not indicate that they had used the crosswalk to analyze claims data.

Comment: Some commenters requested that we maintain the original numbering assignments and labels for certain HCCs or supported using decimals for renumbering. In particular, one commenter cited our proposal regarding HCCs 88 and 89, where we proposed to rearrange the hierarchy between V05 HCC 89 (Reactive and Unspecified Psychosis, Delusional Disorders) and HCC 88 (Major Depressive and Bipolar Disorders) to reflect higher cost similarities between the V05 HCC 89, which described psychotic disorders, and HCC 87 which described schizophrenia. In addition to proposing changes to the hierarchy and modifications to the names of the HCCs, we also proposed switching the numbers for HCCs 88 and 89 so that the numbering sequence between 87, 88, and 89 would reflect the change in

³⁶ The estimated difference in risk scores was calculated between the 2020 benefit year factors and the 2021 benefit year factors using the 2017 benefit year enrollee-level EDGE data.

³³ These principles are also repeated earlier in this rule.

hierarchy and the incremental cost differences between schizophrenia, delusional disorders, and depression, respectively. This commenter recommended that we rename these HCCs using decimals (instead of the proposed renumbering).

Response: As explained above and in Table 1, we proposed to switch the numbering for HCC 88 and HCC 89 in response to other updates to the hierarchy positions for mental health HCCs. However, after consideration of comments received, we are not finalizing the proposed renumbering. We agree with commenters that changing the numbering or associated labeling of existing HCCs can be confusing and potentially lead to unnecessary errors in certain circumstances. In response, we are finalizing the revised hierarchy and name changes for these conditions as proposed, but we are not finalizing the renumbering of these HCCs as proposed. Instead, in V07, we are retaining the previous V05 numbering for HCC 88 (Major Depressive and Bipolar Disorders), but are renaming it as proposed (Major Depressive Disorder, Severe, and Bipolar Disorders), and are renumbering and renaming previous V05 HCC 89 (Reactive and Unspecified Psychosis, Delusional Disorders) as HCC 87.2 (Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis) to retain its proposed position above HCC 88 in the hierarchy. To accommodate these changes, we are also renumbering Schizophrenia from the previous V05 numbering of HCC 87 to HCC 87.1 to maintain its place in the hierarchy.

Comment: Some commenters objected to some of the newly added HCCs, including those for fractures, third degree burns and major skin conditions, coma and severe head injury, traumatic amputations, necrotizing fasciitis, and pancreatitis, on the basis that these conditions reflect “acute” diagnoses that issuers are unable to select against and whose associated costs are (or should be) incorporated into all issuers’ pricing assumptions. A subset of these commenters suggested that HHS separate acute and chronic spending in the risk adjustment models if HHS finalizes the HCCs for acute conditions as proposed.

Some comments also suggested that adding or revising HCCs to include the costs associated with acute conditions would be contrary to the risk adjustment program’s fundamental principles because they represent unpredictable risk that issuers cannot adversely select against. One of these commenters stated that the costs associated with acute

conditions are (or should be) already incorporated into all issuers’ pricing assumptions. The commenter further stated that adding these acute condition HCCs to risk adjustment would likely increase the scope of conditions that might affect an issuer’s transfer burden, especially given the national-level predictions of these conditions. The commenter also raised concern that these proposed changes would reduce issuer pricing accuracy, thereby, incentivizing issuers to increase premiums higher than necessary to ensure risk is mitigated. This commenter stated that the incorporation of the cost of acute conditions in demographic factors was more consistent with the principles of risk adjustment and would reflect the more random distribution of acute conditions. One commenter, who supported the proposed changes, noted that traumatic amputation is commonly miscoded by providers as traumatic when it should have been captured as acquired.

Response: We continue to believe that the conditions identified by these commenters (fractures, third degree burns and major skin conditions, coma and severe head injury, traumatic amputations, necrotizing fasciitis, and pancreatitis) should be included in the risk adjustment models and are finalizing these additions and revisions as proposed. Based on our analysis, these conditions indicate the presence of underlying chronic conditions and frailty, are underpredicted in the models, and have high costs in the year after the diagnosis. Therefore, we do not agree that including the new and revised HCCs for fractures, third degree burns and major skin conditions, coma and severe head injury, traumatic amputations, necrotizing fasciitis, and pancreatitis challenges the foundational principle of the risk adjustment program. There is evidence of ongoing chronic costs associated with these conditions, and issuers can potentially adversely select against enrollees with a higher risk of developing these conditions in a given benefit year. In addition, many of these HCCs are also incorporated in Medicare’s prospective CMS–HCC models.

Several HHS–HCCs related to these conditions were reconfigured or newly added to the risk adjustment models to better predict costs for conditions that have near-term ongoing costs. These included HCC 226 (Hip and Pelvic Fractures), HCC 228 (Vertebral Fractures without Spinal Cord Injury), HCC 218 (Extensive Third Degree Burn), HCC 219 (Major Skin Burn or Condition), and HCC 223 (Severe Head Injury). Because there are ongoing costs of care for these

conditions that present risk of adverse selection for plans in the following benefit year, we believe that it is important to reconfigure and add these HCCs to the risk adjustment models given the coding changes made between the ICD–9 and ICD–10 and our review of the enrollee-level EDGE data. We also note that the proposed adoption of the new or reconfigured HCCs for the conditions identified by commenters as “acute conditions” aligns with the general approach in the current models, which separates out acute and chronic spending, if possible, when necessary to improve risk prediction. In addition, 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 would end up in the associated longer term HCCs.

For example, for the traumatic amputation HCC, which we are finalizing for inclusion in the risk adjustment models as proposed, we analyzed and considered different configurations of the amputation-related HCCs during the reclassification process. We proposed and are finalizing two amputation related HCCs: HCC 234 (Traumatic Amputations and Amputation Complications), which is newly added in V07, and HCC 254 (Amputation Status, Upper Limb or Lower Limb), which was a payment HCC in V05. These HCCs were reconfigured to better account for the cost distinctions between the initial treatment, early follow-up, and potential early complications, and the much lower long-term ongoing costs of amputated limbs. Conditions with both acute treatment and permanent ongoing care, such as spinal cord injuries and major limb amputations, have sets of HCCs containing both initial encounter injury codes and additional care and status codes. Since the V05 classification included only the amputation status and complications payment HCC, some costs of the omitted initial episode codes were pulled in via subsequent encounter codes in HCC 254. For example, 38 percent of adult enrollees with HCC 234 also had HCC 254, and therefore, the prediction for enrollees with only amputation status codes were overpredicted, and enrollees with the initial encounter codes were underpredicted. To address underprediction of the initial encounter codes for traumatic amputations of upper limb or lower limb and to better delineate costs between the initial

episode and those for complications and care for ongoing status care, we are finalizing the amputation HCCs as proposed. Additionally, the inclusion of HCC 234 is consistent with the Medicare HCC risk adjustment models.

Another example of a payment HCC in the current risk adjustment models that reflects what commenters identified as “acute conditions” is Necrotizing Fasciitis, which is a life-threatening condition that may require ongoing care related to the tissue damage. Because of the severity of the condition and intensity of treatment, HCC 54 (Necrotizing Fasciitis) has always been distinguished from the lower severity conditions in HCC 55 (Bone/Joint/Muscle Infections/Necrosis) but due sample size issues, these HCCs were grouped in the V05 classification. As noted in the HHS–HCC Updates Paper, we found that HCC 54 (Necrotizing Fasciitis) is clinically distinct and has been underpredicted in the adult and child models with its incremental expenditures that when ungrouped are approximately twice as high as HCC 55 (Bone/Joint/Muscle Infections/Necrosis), and now HCC 54 (Necrotizing Fasciitis) has a sufficient sample size to remove the HCC Group between HCC 55 (Bone/Joint/Muscle Infections/Necrosis) and HCC 54 (Necrotizing Fasciitis) in the adult models. For these reasons, we proposed and are finalizing ungrouping HCC 54 (Necrotizing Fasciitis) and HCC 55 (Bone/Joint/Muscle Infections/Necrosis) in the adult models to better distinguish costs for both HCCs. However, because HCC 54 (Necrotizing Fasciitis) has a low sample size in the child models, we are retaining the HCC Group for HCC 54 (Necrotizing Fasciitis) and HCC 55 (Bone/Joint/Muscle Infections/Necrosis) in the child models.

For the pancreatitis HCCs, on the other hand, we proposed and are finalizing a reconfiguration to HCC 47 (Acute Pancreatitis) to differentiate higher cost conditions within the HCC and a revision to HCC 18 (Pancreas Transplant Status/Complications) to remove the pancreatitis HCCs from HCC 18’s hierarchy exclusions. We are finalizing this exclusion change because pancreas transplants are done primarily for diabetes and insulin conditions rather than pancreatitis, and ICD–9 had a pancreas-specific code for transplant complications, whereas the ICD–10 code set for other transplant complications is not restricted to pancreas transplants. Additionally, we are relabeling HCC 18 (Pancreas Transplant Status/Complications) to HCC 18 (Pancreas Transplant Status) to accurately reflect its ICD–10 code content. As described in

the HHS–HCC Updates Paper, these changes resulted in significant changes in the count and estimated costs for the pancreatitis HCCs in all models. Specifically, the removal of the intestinal malabsorption and other pancreatic disorders from the HCC 47 (Acute Pancreatitis) led to large shifts in sample size and costs, but we believe this reconfiguration of the HCC more accurately captures the risk and costs of acute pancreatitis events that may cause adverse selection issues. We are therefore finalizing the changes to the pancreatitis HCCs as proposed.

We also assessed whether HCCs associated with several of the proposed HCC conditions³⁷ should be added to the models by analyzing enrollees with the given HCC in 2009 MarketScan® data and the costs associated with those enrollees in the subsequent year’s data, 2010 MarketScan® data. The purpose of this analysis was to assess whether the enrollee costs for these conditions, including several conditions that commenters identified as “acute conditions,” persisted over both benefit years. We found that enrollees with these conditions were characterized by persistently higher costs in the subsequent year, 2010.³⁸ This analysis further supports our position that certain HCCs, including several conditions that commenters identified as “acute conditions,” involve ongoing follow-up care, were identified as being persistently underpredicted in the current models and should be modified to improve model prediction and better capture the longer-term costs associated with the conditions. This evidence of ongoing chronic costs associated with these conditions, reaffirms that issuers can potentially adversely select against the risk of enrollees with these conditions. Thus, because we believe it is important and consistent with the objectives of the risk adjustment program to improve model prediction and mitigate risk of adverse selection

³⁷ This analysis assessed the following HCCs: HCC 18 (Diabetes with Chronic Complications), HCC 19 (Diabetes without Complication), HCC 20 (Type I Diabetes Mellitus), HCC 80 (Coma, Brain Compression/Anoxic Damage), HCC 161 (Chronic Ulcer of Skin, Except Pressure), HCC 162 (Severe Skin Burn or Condition), HCC 163 (Moderate Skin Burn or Condition), HCC 166 (Severe Head Injury), HCC 167 (Major Head Injury), HCC 169 (Vertebral Fractures without Spinal Cord Injury), HCC 170 (Hip Fracture/Dislocation), HCC 173 (Traumatic Amputations and Complications), HCC 189 (Amputation Status, Lower Limb/Amputation Complications), and HCC 190 (Amputation Status, Upper Limb).

³⁸ We used MarketScan® data for this analysis as we currently are unable to link enrollees year over year in enrollee-level EDGE data. In the future, we expect to be able to link enrollees year over year in the enrollee-level EDGE data, if the individuals are enrolled with the same issuer over the years.

when possible, we believe the newly added or reconfigured HCCs discussed above are consistent with our prior framework for payment HCCs, and we are finalizing the updates related to ICD–10 reclassifications of HCCs that are described in this final rule in Table 2.

Comment: One commenter stated that severe head injury HCC 223 (Severe Head Injury) should not be added to the adult and child risk adjustment models because associated chronic costs are captured in existing HCC 122 (Coma/Brain Compression). Another commenter agreed with including the new HCC 223 (Severe Head Injury) but requested that we exclude the acute costs from the chronic costs associated with the underlying diagnoses.

Response: We disagree with the comment that HCC 223 (Severe Head Injury) should not be added in the models because existing HCC 122 (Non-Traumatic Coma and Brain Compression/Anoxic Damage) already captures the applicable chronic costs associated with these conditions. Although there is overlap between HCC 122 and HCC 223, the inclusion of HCC 122 alone is not sufficient in representing the costs of Severe Head Injury.

We also note that due to difficulty in distinguishing between acute and chronic costs for these HCCs, we are not separating the acute costs from chronic costs for these HCCs. 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.

In the HHS–HCC Updates Paper, we noted that HCC 223 represents a condition with ongoing care costs, similar to other injury HCCs currently included in the current risk adjustment models (for example, hip fractures and vertebral fractures). We explained that the new HCC 223 would be included in a hierarchy above HCC 122 (Coma/Brain Compression, Anoxic Damage).³⁹ In the child models, due to small sample size, HCC 223 (Severe Head Injury) would be constrained with *a priori* logic to HCC 218 (Extensive Third Degree Burns) so that the HCCs are counted individually, but have the same coefficient. We continue to believe that the proposed addition of HCC 223, along with the constraints described, are appropriate updates to the HHS–HCC reclassification and are similar to the payment HCCs under the Medicare risk

³⁹ In all models, HCC 122 would be relabeled to “Coma/Brain Compression, Anoxic Damage” to account for the ongoing inclusion of coma codes that may be associated with a traumatic injury.

adjustment models. We are therefore finalizing these changes as proposed.

Comment: While one commenter supported the inclusion of two new HCCs for third degree burns with the recommendation to separate acute costs from ongoing costs, other commenters opposed the proposed changes. Commenters noted that these are random acute events and that the chronic costs associated with third degree burns are separately identifiable. One commenter also suggested that the inclusion of burn HCCs as payment HCCs would lead to upcoding due to higher acute costs than ongoing costs.

Response: In the HHS–HCC Updates Paper, we noted that HCC 218 (Severe Skin Burn or Condition) and HCC 219 (Moderate Skin Burn or Condition) were identified as being underpredicted in the current models and contain chronic conditions or burns that involve long-term follow-up care. To further explore the relationship between these HCCs (HCC 218 and HCC 219) and long term costs, we analyzed Marketscan® data, and found that the presence of these HCCs in 2009 was associated with persistently higher costs in the subsequent year, 2010. The addition of these HCCs to the payment models, as proposed, is also consistent with our goals to improve model prediction and keep with the risk adjustment goal of identifying chronic or systematic conditions that represent insurance risk selection or risk segmentation. However, the ability to separate costs associated with the acute event and chronic condition can be complex for certain HCCs, and in the case of the burn-related HCCs, the enrollees may have chronic conditions or burns that require ongoing follow-up care that is difficult to separate out. For this reason, we are not separating out the costs between the initial acute event and chronic condition.

We are also finalizing the labeling of these HCCs as proposed to reflect the reconfiguration of these HCCs consistent with the ICD–10 updates. Specifically, we reconfigured HCC 218 (Extensive Third Degree Burns, formerly Severe Skin Burn or Condition) to only contain extensive third burns and HCC 219 (Major Skin Burn or Condition, formerly Moderate Skin Burns or Conditions) to contain less extensive third degree burns by site, extensive non-third degree burns, and other serious and chronic skin condition. For these reasons, we are finalizing these changes as proposed.

Comment: While one commenter appreciated the proposed updates to the substance use HCCs, other commenters opposed the proposed substance use

HCC changes. Some of the commenters observed that some providers are reluctant to use complete and accurate coding for substance use disorders due to the sensitive nature of the diagnoses. Other commenters also stated that separating out the current V05 HCC 81 (Drug Psychosis) and HCC 82 (Drug Dependence) into five separate HCCs with distinct, ungrouped, coefficients in the adult models rewards poor quality of care and may increase incentives for providers to report additional diagnoses. For example, one commenter noted that an issuer with a high number of enrollees with proposed HCC 85 (Mild and Uncomplicated Drug Use Disorder) to an issuer with some enrollees with proposed HCC 82 (Moderate Drug Use Disorder or with Non-Psychotic Complications), could be a case where differences with complications could be the result of members' selection behavior, poor quality care or issuers' ability to influence provider coding or market segmentation. Some commenters supported retaining the two current substance use HCCs (with constrained coefficients), noting concerns that collecting adequate provider documentation at a new more detailed level of specificity will be a challenge given that the current two HCCs have high error rates in RADV. These commenters also expressed the belief that the proposed changes would not add value in measuring an issuer's risk level.

Response: We understand issuers' concerns regarding challenges in coding substance use disorders. We do, however, believe it is important to distinguish among different types of drug and alcohol use. Our analysis of the data (for example, the 2016 and 2017 enrollee-level EDGE data) indicates that there is a large difference in the costs associated with treatment for an individual with a general, nonpsychotic drug use disorder compared with an individual with alcohol use disorder, either with or without psychosis. Therefore, we are finalizing the proposed revisions to update HCC 81 from Drug Psychosis to Drug Use with Psychotic Complications, to update HCC 82 from Drug Dependence to Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications, as well as to add the new HCC 83 (Alcohol Use with Psychotic Complications) and new HCC 84 (Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications), with the exception of modifications described below with respect to grouping these HCCs in the

adult models. Nevertheless, we also agree with commenters that there appears to be limited additional benefit at the present time to distinguish mild drug use disorder, proposed HCC 85 (Drug Use Disorder, Mild, Uncomplicated, Except Cannabis), from other substance use disorders in the revised adult, child, and infant models. We also share commenters' concerns about the possibility of creating incentives for increased reporting of additional diagnoses. We also agree with commenters who suggested that further review of HCC 85 is necessary, including within the context of RADV, prior to adding to this HCC. Therefore, after consideration of comments received, we are not finalizing the addition of HCC 85 in any of the models (adult, child, infant).

In further acknowledgement of commenters' concerns, we are not finalizing our proposal to omit grouping of substance use codes in the adult models and are instead finalizing the grouping parallel to what was proposed for these HCCs in the child models. In both the child and adult models that are being finalized in this rule, HCC 81 (Drug Use with Psychotic Complications) and HCC 82 (Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications) will be grouped, and HCC 83 (Alcohol Use with Psychotic Complications) and HCC 84 (Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications) will be grouped.⁴⁰ We believe that the grouping of drug use and alcohol use HCCs, as finalized in this rule, will help to mitigate any potential incentives that could influence provider coding of these HCCs.

Comment: Some commenters did not agree with mapping P040 (Newborn affected by maternal anesthesia analgesia in pregnancy, labor, and delivery) to the revised HCC 82 (Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications), stating that, unlike the effects on infants of opioid addiction or fetal alcohol syndrome, complications from anesthesia exposure are the product of poor quality of care, and that adding it to the models eliminates incentives to reduce complications from anesthesia such as reducing unnecessary use. One commenter stated that the inclusion of P040 will dilute the predictive value of the coefficient when applied to newborns that were exposed to opioids or alcohol, potentially creating more selection issues.

⁴⁰ Proposed group number G09B included proposed HCCs 83, 84 and 85.

Response: Consistent with the discussion in the HHS–HCC Updates Paper, we proposed to continue to include all substance use disorder payment HCCs in the infant models. Although most infants who are affected by the mother’s substance use via placenta or breast milk are coded with a newborn-specific ICD–10 code from the P04 set, which in the finalized reclassified HHS–HCC updates maps to HCC 82, some infants are coded with substance use codes from the ICD–10 F10–F19 code sets, which map to payment HCCs 81–84 or to non-payment HCCs in the finalized V07 reclassified HHS–HCC updates. To be complete and map the entire set of P04 codes consistently, the diagnosis code P040 Newborn affected by maternal anesthesia and analgesia in pregnancy, labor and delivery was proposed to be added to the infant model within a payment HCC. The substance use disorder HCCs include substance use disorder codes and codes related to effects of noxious substances on infants. Therefore, we are finalizing the substance use disorder payment HCCs with the P040 code mapped to HCC 82 in the infant models to account for these costs and associated risks.

Comment: One commenter specifically opposed the addition of drug poisoning diagnoses to HCC 82 because, they stated, it reflects an acute condition with different patterns of claims, costs, and clinical behavior than other diagnoses in HCC 82. According to the commenter, the majority of drug poisoning diagnoses result from addiction to non-prescribed opioids, and the absence of a prior claim in such circumstances makes the diagnosis difficult to predict. The commenter further observed that an episode of drug poisoning offers a unique opportunity for the enrollee to receive coordinated, high quality care that can help prevent another drug poisoning diagnosis. Lastly, the commenter stated that, because a drug poisoning diagnosis is sometimes the byproduct of a drug addiction associated with treatment for a serious condition, such as cancer, the cost profile for such enrollees will differ from other drug poisoning diagnoses.

Response: We recognize that enrollees with substance use disorders require varied and complicated care. As we showed in the HHS–HCC Updates Paper, however, our estimate of the cost parameter for the revised HCC 82, which includes drug poisoning diagnoses, was not markedly different from the estimate for the current HCC 82 from the same analysis. We do not agree, therefore, that drug poisoning diagnoses are necessarily substantively

different in terms of costs from other drug use disorders in that HCC. Additionally, the risk adjustment models adjust for the costs of additional complicating diagnoses, such as cancer, by including HHS–HCCs related to those conditions.

We agree with the commenter that a drug poisoning diagnosis is an opportunity for improving care management and coordination for an enrollee. The primary objective of the risk adjustment program is to improve model prediction and mitigate risk of adverse selection when possible and, insofar as the addition of drug poisoning diagnoses to HCC 82 represents avoidable risk, we believe it is important to include these diagnoses in the models.

Comment: Some commenters appreciated our proposed modifications to HCCs related to pregnancy, in which we added several HCCs to recognize ongoing care for pregnancy, distinguishing between severity of complications. One commenter requested more data from HHS to substantiate the addition of several new HCCs for ongoing pregnancy (HCCs 210–212)⁴¹ with and without delivery, stating that it is unclear how this will impact risk selection and future year premiums. Another commenter stated that, along with changes to acute conditions, the proposed modifications to HCCs related to pregnancy may incentivize upcoding. However, this commenter also stated that pregnancy as a condition is often planned, and as such, may allow costs associated with pregnancy to be predicted early enough that a person has an opportunity to enroll or change coverage, providing a rationale for including HCCs associated with pregnancy as payment HCCs.

Response: We appreciate the comments agreeing with the proposed modifications to HCCs related to pregnancy and are finalizing these HCCs as proposed. We reconfigured the pregnancy HCCs in the adult and child models to reflect the changes in ICD–10 classification systems over the prior ICD–9 classification related to episode of care, multiple gestation, and ectopic or molar pregnancy complications, as described in the HHS–HCC Updates Paper. Our analysis found that the current set of pregnancy HCCs in the existing models do not account well for a variety of pregnancy scenarios. For example, if an enrollee was pregnant

during a plan year, with a complicated pregnancy as her only HCC, under the current models, she only receives the age-sex coefficient, which results in an underprediction of risk. If an enrollee had a low severity miscarriage HCC or completed pregnancy HCC, she receives one average HCC coefficient (in addition to an age-sex coefficient) in the current models, which results in a slight overprediction of risk. The primary purpose of the changes to the pregnancy HCCs, including the ungrouping of the ectopic/miscarriage-related HCCs and the delivery and post-partum related HCCs and the addition of new HCCs 210–212, is to more precisely account for the costs associated with the pregnancy and with delivery/postpartum, as complications during pregnancy could be unrelated to complications in delivery/postpartum. We are therefore finalizing these changes as proposed for the adult models. For the child models, as explained above, we are finalizing these changes as proposed, except for the removal of HCC 212 from the ongoing pregnancy group because it has sufficient sample size for this population.

Comment: Some commenters generally supported the proposed HCC updates, however other commenters did not support the HCC changes to the risk adjustment models. Some of these commenters requested that HHS delay the implementation of the HCC changes until issuers receive additional data to estimate the impact of specific HCC updates, such as on statewide average risk scores and payment transfers, and if finalized, one commenter suggested that we phase-in the updates. Comments also suggested that HHS develop an ongoing monitoring policy with respect to claim submissions to identify any possible gaming of the revised classifications. Others comments were concerned that the HCC changes may only serve to add more volatility to RADV. One commenter generally opposed all changes to HCCs and requested that we revisit whether the proposed changes violate the principles of risk adjustment.

Some commenters supported specific HCC changes or supported specific HCC changes contingent on additional data analysis. For example, one commenter asked that HHS provide further information on the change to HCC 47, which filters out all but acute pancreatitis. Additionally, some commenters wanted analysis on the blood disorder HCC changes and metabolic and endocrine disorder changes contingent on additional analysis of expensive new treatments

⁴¹ The new pregnancy related HCCs include HCC 210 for (Ongoing) Pregnancy without Delivery with Major Complications, HCC 211 for (Ongoing) Pregnancy without Delivery with Complications and HCC 212 for (Ongoing) Pregnancy without Delivery with No or Minor Complications.

(such as gene therapy). Some commenters supported the addition of the Diabetes Type 1 HCC to the adult models while one commenter did not. Likewise, some commenters supported the asthma HCC change, but one commenter was concerned that splitting the asthma HCC might create opportunities for gaming.

Response: In considering these concerns, we weighed the competing goals of improving predictive power and limiting discretionary coding. We believe it is important to implement these changes as soon as possible to better reflect the HHS–HCCs with the ICD–10 coding changes, which were implemented in 2015. Additionally, some of these changes are already in effect for the Medicare risk adjustment program, and the HHS classification has lagged in the classification changes associated with the ICD–10 coding changes. As such, we are finalizing these changes as proposed, with the exception of modifications described above.

As previously discussed, we provided stakeholders with advance notice of potential HCC changes in the HHS–HCC Updates Paper, released on June 17, 2019. This paper previewed potential HCC changes with detailed estimated costs between the V05 and the V06a classification, as well as the impact of the changes on the adult, child and infant risk adjustment models. With the proposed rule, we also provided stakeholders with a crosswalk of ICD–10 codes to the proposed HCCs under the “Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year,” which is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html>.⁴² Furthermore, in the HHS–HCC Updates Paper, we detailed the impact of the V06a HCC changes in counts of enrollees with and without HCCs. For all of these reasons, we do not believe delaying the implementation of these HCCs for additional data is needed.

We do not extract state identifiers in the enrollee-level EDGE data, and therefore, we are unable to directly assess state level impacts. However, we will consider for future rulemaking proposing to extract state identifiers in

⁴² The Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year includes Table 4, which crosswalks ICD–10 codes to the Condition Categories (CCs) in the risk adjustment models, and Table 5, which provides the hierarchy rules to apply to the CCs to create HCCs. These Tables are similar to the Tables 3 and 5 that HHS includes as part of the HHS-Developed Risk Adjustment Model Algorithm “Do It Yourself (DIY)” Software.

the enrollee-level EDGE data to conduct analyses commenters requested and evaluate changes in risk adjustment models.

With respect to monitoring changes in claims submissions associated with revised HHS–HCC classifications to identify possible gaming, we agree on the importance of maintaining the integrity of the risk adjustment program. We note that there are several existing processes and programs that are intended to ensure program integrity. In addition to RADV, whose principal objective is to identify instances in which a diagnosis submitted to an issuer’s EDGE server for risk adjustment is not supported by clinical documentation, we conduct ongoing quality and quantity review of EDGE submissions, and we carefully analyze annual enrollee-level EDGE data for shifts in diagnoses and spending. In addition, § 153.620(b)(9)(iii) and (iv) provides HHS authority to impose civil money penalties for misconduct, as well as the intentional or reckless misrepresentation or falsification of information furnished to HHS, which could be leveraged if there is evidence of gaming of the revised classifications. Should we determine that any changes to the HHS–HCC classification or other program requirements are necessary to address gaming concerns, we would pursue those modifications through notice-and-comment rulemaking.

In response to comments, we clarify that the V07 changes finalized in this rule will not be applicable in RADV until the 2021 benefit year (consistent with the adoption of the changes for the 2021 benefit year of risk adjustment). As noted above, we believe it is important to implement these changes as soon as possible to align the HHS-operated risk adjustment models with the ICD–10 coding changes, which were implemented in 2015, and do not believe the changes will add more volatility to RADV.

ii. Other Updates to Risk Adjustment Model Recalibration

As discussed in the proposed rule, for the 2020 benefit year adult models, we made a pricing adjustment for one RXC coefficient for Hepatitis C drugs.⁴³ In the 2020 Payment Notice, we stated that we intend to reassess this pricing adjustment in future benefit years’ model recalibrations with additional years of enrollee-level EDGE data.⁴⁴ For the 2021 benefit year model recalibration, we reassessed the Hepatitis C RXC to consider whether the

⁴³ 84 FR 17454 at 17463 through 17466.

⁴⁴ Ibid.

adjustment was still needed, or needed to be modified. We found that the current data for the Hepatitis C RXC still does not take into account the significant pricing changes due to the introduction of new Hepatitis C drugs and, therefore, it does not precisely reflect the average cost of Hepatitis C treatments applicable to the benefit year in question. 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 and, therefore, make the risk adjustment transfer results more favorable for the issuer. For these reasons, we noted that we continue to believe that a pricing adjustment is needed for this RXC coefficient and proposed to adjust the Hepatitis C RXC for the 2021 benefit year model recalibration. For the proposed RXC coefficients listed in Table 2 of the proposed rule, we constrained the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs. Similar to the adjustment for the 2020 benefit year model recalibration, this has the material effect of reducing the Hepatitis C RXC, and the RXC–HCC interaction coefficients. For the final 2021 benefit year Hepatitis C factors in the adult models, we proposed to make an adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing of these drugs before solving for the adult model coefficients. We sought comment on this proposal.

In light of the recent recommendation by the U.S. Preventive Services Task Force (USPSTF) to expand the use of pre-exposure prophylaxis (PrEP) as a preventive service that must be covered without cost sharing by applicable health plans for persons who are at high risk of HIV acquisition,⁴⁵ we also proposed to incorporate PrEP as a preventive service in the simulation of plan liability for HHS’s adult and child risk adjustment models in the final 2021 benefit year model recalibration.⁴⁶ Although preventive services are incorporated in the simulation of plan

⁴⁵ Final Recommendation Statement on “Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis. U.S. Preventive Services Task Force. June 2019. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

⁴⁶ The June 11, 2019 “Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendations Statement” published in JAMA states that adolescents at high risk of HIV acquisition could benefit from PrEP and it is approved for adolescents who weigh at least 35kg (–77 pounds). <https://jamanetwork.com/journals/jama/fullarticle/2735509>.

liability, they do not directly affect specific HCCs. We incorporate preventive services into the models to ensure that 100 percent of the cost of those services is reflected in the simulation of plan liability; preventive services are applied under relevant recommended conditions or groups. We proposed including PrEP as a preventive service along with our general updates to preventive services in the simulation of plan liability for the HHS risk adjustment models in the final 2021 benefit year adult and child models. We sought comment on this proposal.

As part of the proposed 2021 model recalibration, we also considered whether to add an additional age-sex category for enrollees age 65 and over as part of the recalibration of the adult models. MarketScan® data does not include enrollees who are age 65 and over, but the enrollee-level EDGE data does. Currently, the risk adjustment program incorporates the risk and costs of enrollees age 65 and over using the 60–64 age-sex coefficients. We originally excluded enrollees age 65 and over from recalibration to prevent having different methodologies for the MarketScan® and the enrollee-level EDGE datasets that were used to solve for the blended coefficients for the risk adjustment models.

Since we proposed to no longer use the MarketScan® data to recalibrate the risk adjustment models beginning with the 2021 benefit year, we explained in the proposed rule that we considered whether new age-sex coefficients should be created for enrollees age 65 and over beginning with the 2021 benefit year adult models. In reviewing the enrollee-level EDGE data, we found that over 70 percent of the enrollees age 65 and over are within the 65–66 age range, and we believe these enrollees are likely transferring into Medicare coverage once eligible. Our analysis also found that the enrollees ages 65–66 have lower average annual expenditures than those enrollees between ages 60 and 64. In contrast, we found that enrollees age 67 and over have higher average annual expenditures than those between ages 60 and 64. Due to these two different trends in the age 65 and over population, we did not propose to add new age-sex coefficients to the adult models at this time and would continue to exclude enrollees age 65 and over in the adult models' calibration for the 2021 benefit year. We also noted that we would continue to monitor expenditures for enrollees age 65 and over to determine whether the addition of new age-sex coefficients to the adult models in a future year is appropriate.

After reviewing the comments we received, we are finalizing our proposal to apply an adjustment to the plan liability for the final 2021 benefit year Hepatitis C factors in the adult models to ensure that enrollees can continue to receive incremental credit for having both the RXC and HCC for Hepatitis C, and allow for differential plan liability across metal levels. We will release the final RXC coefficients that reflect constraining the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs in guidance, along with the other final 2021 benefit year coefficients, by June 2020 to allow for incorporation in final rates for the 2021 benefit year, consistent with § 153.320(b)(1)(i).

We are also finalizing our proposal to incorporate PrEP as a preventive service in the simulation of plan liability for HHS's adult and child risk adjustment models in the final 2021 benefit year model recalibration. We did not propose to add new age-sex coefficients to the adult models and are not making any changes to age-sex coefficients for enrollees age 65 and over at this time.

The following is a summary of the public comments we received on the proposed pricing adjustment for the Hepatitis C RXC for the adult models, the proposal to incorporate PrEP as a preventive service in the simulation of plan liability for the adult and child models, and the discussion of the age-sex coefficients in the adult models. We also respond to other comments suggesting additional modifications to the HHS risk adjustment models.

Comment: Most commenters supported the pricing adjustment for the Hepatitis C RXC. These commenters reasoned that this pricing adjustment 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 did not support this proposal, and suggested HHS avoid artificially constraining plan payment until prescription denial rates decrease and to account for potential adverse selection associated with treatment for Hepatitis C Virus (HCV). This commenter also expressed concern about HHS manually adjusting the risk adjustment coefficients downwards, potentially penalizing plans that provide better coverage for innovative drugs. Another commenter recommended HHS clarify the data source and approach it is using to constrain the Hepatitis C RXC coefficient, and cautioned against

reducing the coefficient more than the expected decrease in cost.

Response: In response to comments, we reassessed the pricing adjustment for the Hepatitis C RXC for the 2021 benefit year model recalibration and found that the most recent year of data (2018 enrollee-level EDGE data) for the Hepatitis C RXC still does not take into account the significant pricing changes expected due to the introduction of newer and cheaper Hepatitis C drugs. Therefore, the data that will be used to recalibrate the models does not precisely reflect the average cost of Hepatitis C treatments applicable to the 2021 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, and therefore, make the risk adjustment transfer results more favorable for the issuer. Due to the high cost of these drugs reflected in the 2016, 2017 and 2018 enrollee-level EDGE datasets, without a pricing adjustment to plan liability, issuers would be overcompensated for the Hepatitis C RXC in the 2021 benefit year, and could be incentivized to encourage overprescribing practices and game risk adjustment such that the issuer's risk adjustment payment is increased or risk adjustment charge is decreased. This pricing adjustment helps avoid perverse incentives, and leads to Hepatitis C RXC coefficients that better reflect anticipated actual 2021 benefit year plan liability associated with Hepatitis C drugs. It is also consistent with the approach adopted for the 2020 benefit year recalibration to address these concerns.

As such, we are finalizing our proposal to make a pricing adjustment to more closely reflect the expected average additional plan liability of the Hepatitis C RXC for the 2021 benefit year adult risk adjustment models. In making this determination, we consulted our clinical and actuarial experts, and analyzed the most recent enrollee-level EDGE data available (2018 benefit year) to further assess whether lower cost Hepatitis C drugs can be substituted to ensure that plans that cover various treatments would continue to be compensated for their incremental plan liability. 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: Some commenters asked HHS to monitor the market 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. These commenters expressed concern about adequate issuer compensation for these drugs and the potential for adverse selection. The comments noted that the costs of very new, high cost treatments will not be reflected in prior year EDGE claims data.

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 intend to assess this issue as additional data becomes available and consider whether model updates should be made to address their anticipated costs in the future. We note that if an enrollee in an issuer's risk adjustment covered plans has 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. Therefore, this issuer would receive compensation for these high-cost treatments under the HHS-operated risk adjustment program in the 2021 benefit year.

Comment: Most commenters supported our proposal to incorporate PrEP as a preventive service in the simulation of plan liability for HHS's adult and child risk adjustment models in the final 2021 benefit year model recalibration. One commenter sought clarity as to whether issuers can offer both the generic and brand drug at \$0 cost sharing. Another commenter requested more information about the incorporation of PrEP into the risk adjustment models, such as how HHS will identify PrEP therapies, given the rapid development of new therapies. Several commenters recommended incorporating PrEP as a prescription drug factor (RXC) in the adult models to adequately compensate plans that disproportionately enroll individuals using PrEP and prevent risk selection, and one commenter requested that HHS disclose any operational issues such as the ability to distinguish between antiretroviral therapy that is provided as a result of HIV acquisition and antiretroviral therapy that is provided as PrEP using logic that would make it difficult to implement an RXC for PrEP. Two commenters also encouraged including recommended ancillary services as part of the PrEP intervention in the risk adjustment models.

Response: We proposed to incorporate 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 USPSTF. We were able to distinguish enrollees that met the "at risk" recommendation in the USPSTF recommendation and were receiving antiretroviral therapy for PrEP, rather than as treatment for HIV/AIDS, in our analysis of the enrollee-level EDGE datasets. We chose not to propose incorporating PrEP as an RXC because, as a general principle, RXCs are incorporated into the HHS risk adjustment adult models to impute a missing diagnosis or indicate severity of a diagnosis.⁴⁷ Currently, PrEP is not incorporated into RXC 1 (Anti-HIV) because PrEP does not indicate an HIV/AIDS diagnosis.⁴⁸ Unlike the other prescription drugs that we have included in RXCs, PrEP does not adequately represent risk due to an active condition. However, we proposed and are finalizing the incorporation of 100 percent of the PrEP costs for enrollees without HIV diagnosis or treatment in the simulation of plan liability for the adult and child models.

The expected upcoming release of a generic version of PrEP will enable issuers to offer both the generic and brand drug at \$0 cost sharing. We recognize that using past enrollee-level EDGE data may not properly predict future costs given the rapid development of new drugs. However, we are only able to analyze the enrollee-level EDGE claims data we have available when developing our proposals to incorporate new preventive services into the risk adjustment models, and do not have claims data on the expected new generic PrEP or any other drugs in development for use for the 2021 benefit year models. Therefore, while our modeling may not identify new PrEP therapies at this time, we were able to analyze the data to identify enrollees taking PrEP without HCC 1 (HIV/AIDS) to attribute those costs at 100 percent of simulation of plan liability.

We did not propose and are not finalizing the addition of PrEP as an RXC to the adult risk adjustment models. It is difficult to model the impact of adding PrEP as an RXC at this time because we expect an increase in the number of people taking PrEP after

⁴⁷ See 81 FR 94058 at 94075. Also see March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers, June 8, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf>.

⁴⁸ See <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf>; <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf>.

the recent recommendation by the USPSTF Task Force to expand the use of PrEP as a preventive service, and we anticipate price changes with the expected upcoming release of a generic version of PrEP. Further, as noted above, as a general principle, RXCs are incorporated into the adult risk adjustment models to impute a missing diagnosis or indicate severity of a diagnosis. Since the use of PrEP is currently recommended as a preventive service for persons who are not infected with HIV and are at high risk of HIV infection, the use of PrEP does not indicate a diagnosis, and it would be inconsistent with this principle to add it as an RXC at this time.

Additionally, we did not propose changes to the risk adjustment methodology related to ancillary services associated with PrEP as requested by two commenters. Therefore, we are not finalizing any changes to the treatment of ancillary services under the risk adjustment models for the 2021 benefit year, but will consider the comments as we consider further refinements to the risk adjustment models for future years.

We are finalizing our proposal to incorporate PrEP as a preventive service in the simulation of plan liability for HHS's adult and child risk adjustment models in the final 2021 benefit year model recalibration and will continue to explore potentially including PrEP as an RXC in future benefit years.

Comment: One commenter requested HHS propose adding new age-sex coefficients to the adult risk adjustment models for enrollees age 65 and over in a future rulemaking, as HHS moves to using exclusively enrollee-level EDGE data to recalibrate the models. Another commenter recommended further analysis of age-sex coefficients for enrollees age 65 and over and noted factors may need to differ by market or by Medicare status.

Response: We appreciate these comments and intend to continue to monitor expenditures for enrollees age 65 and over to determine whether the addition of new age-sex coefficients for this cohort of the population to the adult models in a future year is appropriate. However, we did not propose and are not making any changes to age-sex coefficients for enrollees age 65 and over at this time. We will continue to exclude enrollees age 65 and over in the adult models' calibration for the 2021 benefit year because we believe most of these enrollees are likely transferring into Medicare coverage once eligible.

(3) Improving Risk Adjustment Model Predictions

In the proposed rule, we solicited comment on different options to modify the risk adjustment models to improve model prediction for enrollees without HCCs or enrollees with low actual expenditures for future benefit years as follow-up from our consideration of these issues in the 2018 Payment Notice. More precisely, in the proposed rule, we discussed how, based on the use of the MarketScan® data, the HHS-HCC models under-predict for enrollees without HCCs, slightly over-predict for enrollees with low HCC counts and under-predict for enrollees with the highest HCC counts. In the proposed rule, we explained that we continued to evaluate potential future options to address these issues and the tradeoffs that would need to be made in model predictive power among subgroups of enrollees under these options and that we continued to believe that further evaluation is appropriate before pursuing these options. However, we also recognized that additional stakeholder comment was a critical aspect to this analysis. Therefore, we outlined and solicited comment on various options that we were continuing to consider to improve the models' predictive ability for certain subgroups of enrollees in light of experience and currently available information.

The first option that was detailed in the 2018 Payment Notice⁴⁹ and in the proposed rule involved a constrained regression approach, under which we would estimate the adult risk adjustment models using only the age-sex variables, and then, we would re-estimate the models using the full set of HCCs, while constraining the value of the age-sex coefficients to be the same as those from the first estimation. In the 2018 Payment Notice, we stated that we believed that this two-step estimation approach would result in age-sex coefficients of greater magnitude, potentially helping us predict the risk of the healthiest subpopulations more accurately. However, as noted in the proposed rule, we also found upon further analysis that the mean expenditures of individual HCCs under this approach were under-predicted compared to the current adult models and the mean expenditures of extremely expensive enrollees were more under-predicted under this approach than in the current adult models.

The second option discussed in the proposed rule involved directly adjusting plan liability risk scores

outside of the models for the impacted sub-populations. This approach would involve directly increasing underestimated plan liability risk scores or reducing overestimated plan liability risk scores in an attempt to better match the relative risks of these sub-populations.⁵⁰ Specifically, we evaluated using a post-estimation adjustment to the current models' individual-level risk scores to address the observed patterns of over- and under-prediction for certain sub-populations. In the proposed rule, we stated that while we believed modifications of this type could improve the model's performance along this specific dimension (deciles of predicted expenditures), there was a risk that such modifications could unintentionally worsen model performance along other dimensions on which the model currently performs well. As described in the proposed rule, we recently reassessed this adjustment option given the availability of the more recent enrollee-level EDGE data and the implementation of several updates to the HHS risk adjustment methodology beginning with the 2018 benefit year.⁵¹ We did not find improvements in the predictive ratios when compared to the predictive ratios of the current approach. Our analysis of this adjustment option showed that the estimates for the lowest-cost decile and top two highest-cost deciles of enrollees were more underpredicted under this approach as compared to the current model. Additionally, this approach resulted in worse prediction along other dimensions, such as for subgroups of enrollees with no HCCs and those with 1 or more payment HCCs.

Given the shortcomings with both of these approaches, we ultimately did not propose or adopt either of them. However, in the proposed rule, we explained that we have continued to consider other potential approaches to address the under-prediction of risk for low-cost enrollees and over-prediction for high-cost enrollees. In particular, we have also been examining non-linear and count model specifications to improve the current adult models' predictive power.

Our initial analysis of the non-linear and count model specifications had shown that these alternatives can

improve prediction in the adult models. For the non-linear model, we were considering an option that would add a coefficient-weighted sum of payment HCCs raised to a power to the linear specification. Under this approach, the non-linear term would be added as the exponentiated p term as shown in the following formula:

$$\text{Plan liability} = \text{Current Model} + (\sum \beta_i \text{HCC}_i)^p$$

Where:

$\sum \beta_i \text{HCC}_i$ = the sum of payment HCCs weighted by their parameter estimates;
 p = an exponential factor estimated by the model.

This type of non-linear model would measure the total disease burden by a weighted count of HCCs rather than a simple count of the payment HCCs, while only requiring one additional parameter. This approach would also allow the demographic terms for enrollees with no payment HCCs to be better estimated, while using a nonlinearity for the disease burden that could keep the model reasonably simple. As such, we believed that adding a non-linear term to the models could be a reasonable approach to potentially improve the prediction of the models.

For the count model, we considered adding eight indicator variables corresponding to 1 to 8-or-more payment HCCs. Under this option, the incremental predictions would vary with a person's count of HCCs (from 1 to 8-or-more payment HCCs) as the incremental predictions for HCCs in a HCC count model have two components, the HCC coefficient and the change in the number of HCCs (from 1 to 8-or-more payment HCCs). This option would also generally be more consistent with other programs (Medicare Advantage) than the non-linear model, and has yielded similar results in model performance and improvements in the prediction in the adult models as the non-linear model. However, similar to the non-linear model, the count model may not improve the prediction for all subpopulations in the models.

Additionally, in the proposed rule, we discussed potential adjustments to the enrollment duration factors in the adult models, as well as an assessment of whether such factors should be incorporated into the child and infant models. Using the 2016 and 2017 enrollee-level EDGE data, we investigated heterogeneity in the relationship between partial-year enrollment and predicted expenditures. We explored heterogeneity according to the presence of certain diagnoses,

⁵⁰ Ibid.

⁵¹ For example, we incorporated the high costs risk pool parameters into the HHS risk adjustment methodology, added RXCs into the adult risk adjustment models, and applied an administrative cost reduction to the statewide average premiums in the state payment transfer formula starting with the 2018 benefit year. See the 2018 Payment Notice, 81 FR 94058 (December 22, 2016).

⁴⁹ Ibid.

market (individual or small group),⁵² and 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 current enrollment duration factors are driven mainly by enrollees with HCCs, that is, partial year enrollees with HCCs have higher per member per month (PMPM) expenditures on average as compared to full year enrollees with HCCs, whereas partial year enrollees without HCCs have similar PMPM expenditures compared to their full year counterparts. 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 affect PMPM expenditures on average. Our analysis also found that separate enrollment duration factors by market in the adult models may be warranted, given the differences in risk profiles of partial year enrollees between the individual and small group markets.⁵³ However, due to limitations with the extracted enrollee-level EDGE data for the 2016 and 2017 benefit years that do not permit us to connect non-calendar year enrollees in the small group market across plan years within the same calendar year, we are unable to develop and propose separate enrollment duration factors by market at this time. Based on these analyses, because partial-year enrollees with HCCs seem to have the most distinctive additional expenditures, we explained in the proposed rule that we believed that eliminating the enrollment duration factors and replacing them with monthly enrollment duration factors (up to 6-months), for those with HCCs, would most improve model prediction.

Additionally, in the proposed rule, we analyzed incorporating enrollment duration factors in the child and infant models in the same manner as the adult models. 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 partial year enrollees in the child models tended to have similar risk to full year enrollees in the child models. In the infant models, we found that partial year infants have higher expenditures on average compared to

their full year counterparts. However, we found that the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors in the infant models and did not have a meaningful impact on the general predictive accuracy of the infant models. As such, we did not propose to add partial year factors to the child or infant models.

We solicited comments on all of the alternative modeling approaches to help inform our evaluation of the important trade-offs in making improvements to risk prediction for these sub-populations and providing consistency year-to-year for issuers, but did not propose to incorporate any of them as part of the 2021 benefit year risk adjustment model recalibration. We also generally solicited comments but did not propose any changes to the enrollment duration factors (including the potential addition of such factors to the child and infant models) for the 2021 benefit year. Instead, as outlined in the proposed rule, we intend to use stakeholder comments on these issues to aid in consideration of future model updates as we also continue to analyze these options using additional years of enrollee-level EDGE data, once available. The following is a summary of the public comments we received in response to the solicitation of comments on potential approaches to improve risk adjustment model prediction.

Comment: Commenters generally appreciated or supported HHS's solicitation of comments on revisions to the risk adjustment models to improve model prediction. Some commenters supported evaluating count and non-linear models to address the under- and over-prediction of costs in the current models or generally supported making changes to risk adjustment to better account for enrollees without HCCs and enrollees with the highest number of HCCs in the future. Other commenters expressed concerns about the count and non-linear methods introducing more complexity to the risk adjustment models and creating uncertainty in pricing.

Most commenters wanted additional analyses and various types of data, such as issuer and beneficiary level data, on the impact of any potential model changes on the current risk adjustment program and the improvements in accuracy and predictive power that these models could provide to inform whether these types of changes should be pursued. Some commenters recommended that HHS release a White Paper on its analyses and data prior to rulemaking. Others wanted continued

HHS engagement with stakeholders on model changes aimed at improving the risk adjustment models' predictions. Some commenters recommended more interaction and severity terms, such as a diabetes and asthma interaction term, in the risk adjustment models as a simpler and more stable change to improve model prediction, compared to the count or non-linear model specifications. One commenter supported finding viable alternative methodologies but urged caution in quickly adopting the count or non-linear models before analysis can be fully validated and another commenter expressed concern about the count and non-linear models given that individual and small group market enrollees have less HCCs that could result in smaller sample sizes and bring volatility to the models. One commenter did not think that any of the approaches described in the proposed rule would impact coding incentives in the risk adjustment program beyond those incentives that already inherent to the risk adjustment program. One commenter supported including the model changes in the 2022 risk adjustment models if the prediction for low-risk enrollees is better and stated that it would be helpful if the methodology used was similar to Medicare, while another commenter suggested providing several years lead time before implementing the model change options discussed in the proposed rule.

Response: We agree with commenters who suggested that further evaluation is needed of the model performance before proposing these types of changes to the risk adjustment models. Although we did not receive many comments that were specific to the model options considered, we intend to continue to evaluate alternative modeling approaches to improve model prediction as described in the proposed rule, and would propose any modifications through future rulemaking.

As explained in the proposed rule, our initial analyses suggested that the non-linear and count models may yield considerable gains in predictive accuracy across several groups in the adult models when compared to the current linear model. Based on the initial testing of both the count and non-linear models' impact on the adult silver risk adjustment models, we found that the enrollees with the lowest costs have better predictive ratios under both the count and non-linear models than under the current model, with the non-linear model slightly over-predicting the costs of those enrollees. We also noted that we do not believe that the count or non-

⁵² In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

⁵³ In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

linear models would impact coding incentivizes to code additional HCCs in comparison to the current risk adjustment models.

However, we intend to balance the associated trade-offs of making improvements to the models and providing consistency year-to-year for issuers in the HHS-operated risk adjustment program. As such, we intend to further test the model specifications, incorporating the non-linear and count options described above and consider whether we should analyze other options that could address model prediction, with an additional year of data before considering these model changes for future years and will take into consideration the additional analyses recommended by commenters. Based on those results, and in response to comments, we will also consider what types of analyses or data we could release to help stakeholders assess these options and models for any potential future incorporation into the risk adjustment models.

Comment: Commenters generally supported making updates to the enrollment duration factors to prevent adverse selection with one commenter supporting removal of the enrollment duration factors, suggesting it would simplify risk adjustment. Some commenters wanted additional analyses and data on the potential changes to the enrollment duration factors before modifications were made to the existing factors. Some comments supported separate enrollment duration factors by market since the adverse selection considerations differ in the individual and small group markets or supported applying adjustments only to enrollees with HCCs believing this adjustment could help to differentiate enrollees selecting coverage during a Special Enrollment Period (SEP) from those

enrolling during open enrollment and dropping coverage early in the year without claims. However, one commenter wanted HHS to apply enrollment duration values to the 2021 benefit year for the individual market (but not small group market enrollees) to capture adverse selection and the differences in churn between markets. Some commenters expressed support for incorporation of enrollment duration factors in the infant models since partial-year infants have higher expenditures on average compared to their full-year counterparts.

Response: As discussed in the proposed rule, due to certain data limitations in the 2016 and 2017 enrollee-level EDGE data, we did not propose changes to 2021 benefit year existing enrollment duration factors for the adult models. However, we intend to continue to review the use of enrollment duration factors in the HHS risk adjustment models, both with respect to the current factors in the adult models and the potential incorporation of such factors in the child and infant models. With the availability of more benefit years of enrollee-level EDGE data, we will consider potential changes to the enrollment duration factors for future benefit years, including whether to make changes to the enrollment duration factors to distinguish market type differences or to distinguish partial year enrollees with HCCs. As part of that analysis, we will also continue to assess the infant models' characteristics, and whether we should consider incorporating enrollment duration factors into those models. We intend to consider recommendations and considerations shared by commenters in response to the proposed rule as part of this analysis.

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

We noted in the proposed rule that if we finalize the proposed recalibration approach, we would incorporate the 2018 benefit year enrollee-level EDGE data in the final rule or in guidance after publication of the final rule, consistent with our approach in previous benefit years.⁵⁴ As noted above, we were unable to incorporate the 2018 benefit year EDGE data in time to publish the final coefficients in this final rule. Therefore, for the 2021 benefit year, we will release the final list of coefficients, incorporating the 2018 benefit year enrollee-level EDGE data, in guidance by June 2020, to allow the factors to be incorporated into final rates for the 2021 benefit year.

(5) 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 2021 benefit year, to maintain stability and certainty for issuers, we proposed to maintain the CSR factors finalized in the 2019 and 2020 Payment Notices.⁵⁵ Consistent with the approach finalized in the 2017 Payment Notice,⁵⁶ 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 factors as proposed and will maintain the same CSR factors finalized for the 2019 and 2020 benefit years for the 2021 benefit year as shown in Table 3.

TABLE 3—COST-SHARING REDUCTION ADJUSTMENT

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

⁵⁴ See 45 CFR 153.320(b)(1)(i).

⁵⁵ See 83 FR 16930 at 16953 and 84 FR 17454 at 17478 through 17479.

⁵⁶ See 81 FR 12203 at 12228.

TABLE 3—COST-SHARING REDUCTION ADJUSTMENT—Continued

Household income	Plan AV	Induced utilization factor
<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

The following is a summary of the public comments we received on the proposed CSR factors in the risk adjustment models.

Comment: Many commenters supported the CSR adjustment factors for the 2021 benefit year and continuing the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans. Some commenters wanted HHS to analyze the CSR adjustment factors and induced demand factors for future benefit years to consider whether changes are needed.

Response: We are finalizing the CSR adjustment factors as proposed. Consistent with the approach finalized in the 2017 Payment Notice,⁵⁷ 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 2021 benefit year, as all of Massachusetts’ cost-sharing plan variations have AVs above 94 percent. We have previously reviewed the induced utilization factors with the availability of the enrollee-level EDGE data, and we continue to believe the current CSR adjustments are adequate. However, we will continue to reexamine whether changes to the induced demand factors and CSR adjustments are warranted in the future.

(6) 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.⁵⁸ Because we blended the coefficients from separately solved models based on the 2016 and 2017 benefit years’ enrollee-level EDGE data that were available at the time of the proposed rule, we published the R-squared statistic for each model separately to verify their statistical validity. We noted in the proposed rule that if the proposed 2021 benefit year model recalibration data was finalized, we intended to publish updated R-squared statistics to reflect results from the blending of the 2016, 2017, and 2018 benefit years’ enrollee-level EDGE datasets used to recalibrate the models for the 2021 benefit year. For the 2021 benefit year, we will release the final R-squared statistics along with the final coefficients, incorporating the 2018 benefit year enrollee-level EDGE data, in guidance by June 2020.

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

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.⁵⁹ 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,⁶⁰ 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 under the HHS-operated risk adjustment methodology, rather than a different parameter, such as each plan’s own premium, which would not have automatically achieved equality between risk adjustment payments and charges in each benefit year.⁶¹

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

⁶⁰ 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).

⁶¹ See the 2020 Payment Notice for further details on other reasons why statewide average premium is the cost-scaling factor in the state payment transfer formula. See 84 FR 17454 at 17480 through 17484.

⁵⁷ See 81 FR 12203 at 12228.

⁵⁸ Winkleman, Ross and Syed Mehmud. “A Comparative Analysis of Claims-Based Tools for Health Risk Assessment.” Society of Actuaries. April 2007.

⁵⁹ 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.

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 transfer 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 state payment transfer formula also includes a 14 percent administrative cost reduction to the statewide average premium.⁶²

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 that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers 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.⁶³ 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.

To account for costs associated with exceptionally high-risk enrollees we previously added a high-cost risk pool adjustment to the HHS risk adjustment

transfer methodology. As finalized in the 2020 Payment Notice,⁶⁴ 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 beyond, unless amended through notice-and-comment rulemaking. We did not propose any changes to the high-cost risk pool parameters for the 2021 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 payment transfer formula are calculated as follows:

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

Where:

Total Transfer_i = Plan i 's total HHS risk adjustment program transfer amount;
 T_i = Plan i 's PMPM transfer amount based on the state transfer calculation;
 M_i = Plan i 's billable member months;
 HRP_i = Plan i 's total high-cost risk pool payment;
 $HRPC_m$ = High-cost risk pool percent of premium adjustment factor for the respective national high-cost risk pool m ;
 TP_i = Plan i 's total premium amounts.

We proposed to continue to use the HHS state payment transfer formula that was finalized in the 2020 Payment Notice with no changes.⁶⁵ We noted in the proposed rule that although the proposed HHS state payment transfer formula for the 2021 benefit year is unchanged from what was finalized for the previous benefit year, we believed it is useful to republish the formula in its entirety in the proposed rule.

Additionally, we noted that we republished the description of the administrative cost reduction to the statewide average premium and high-cost risk pool factors, although these factors and terms also remain unchanged in the proposed rule.⁶⁶

We are finalizing our proposal to use the risk adjustment state payment transfer formula finalized in the 2020 Payment Notice for 2021 benefit year risk adjustment. This includes maintaining the 14 percent administrative cost reduction to the statewide average premium for the 2021 benefit year. We also did not propose and are therefore maintaining the threshold of \$1 million and coinsurance rate of 60 percent as the high-cost risk pool parameters for the 2021 benefit year. Below is a summary of comments we received on maintaining the risk adjustment state payment transfer formula and high-cost risk pool parameters finalized in the 2020 Payment Notice.

Comment: Most commenters supported maintaining the high-cost risk pool parameters to promote stability in the risk adjustment program and to fulfill its goals of preventing adverse selection while maintaining a level playing field and facilitating fair market competition on the basis of efficiency and quality of care provided. One commenter did not support maintaining the high-cost risk pool due to concerns that issuers may try to "game" the system by inflating the costs of high-cost services to push payments over the threshold, and stated that the methodology creates another level of uncertainty that issuers will need to factor into their premiums. This commenter stated that if HHS wants to

⁶² This adjustment applied beginning with the 2018 benefit year. See 84 FR 17454 at 17486 for a visual illustration of the equation for this adjustment.

⁶³ 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.

⁶⁴ 84 FR 17454 at 17466 through 17468.

⁶⁵ 84 FR 17454 at 17480 and 17485.

⁶⁶ *Ibid.*

continue the reinsurance program, it should be pursued outside of risk adjustment, and suggested HHS should instead create a permanent reinsurance program, using Medicare pricing to reprice all claims over \$1 million and account for geographic pricing variations in its calculation of the high-cost risk pool payment and charge terms. Another commenter supported exempting new issuers from risk adjustment, applying a creditability approach to risk adjustment participation or placing an upper bound on risk adjustment transfer charges.

Response: We did not propose to make changes to the high-cost risk pool adjustment or parameters in the proposed rule. In the 2020 Payment Notice, we finalized the high-cost risk pool parameters and the additional terms to account for the high-cost risk pool in the risk adjustment transfer methodology for the 2020 benefit year and for future benefit years unless changed in notice-and-comment rulemaking. These parameters will therefore continue to apply in the HHS risk adjustment methodology until HHS proposes to change them. As explained in prior rulemakings, we added a high-cost risk pool adjustment in the HHS risk adjustment methodology to better account for the risk associated with high-cost enrollees and to allow the risk adjustment factors to be calculated without the high-cost risk, since the average risk associated with HCCs and RXCs is better accounted for without the inclusion of the high-cost enrollees.⁶⁷ We did not propose nor are we finalizing the creation of a new, separate reinsurance program.

Furthermore, we continue to believe a \$1 million threshold and 60 percent coinsurance rate for the 2021 benefit year and beyond are appropriate to incentivize issuers to control costs while improving risk prediction under the HHS risk adjustment models and prevent any potential gaming of issuers to inflate costs. We also believe the \$1 million threshold and 60 percent coinsurance rate will result in total high-cost risk pool payments or charges nationally that are very small as a percentage of premiums for issuers, and will prevent states and issuers with very high-cost enrollees from bearing a disproportionate amount of unpredictable risk. Lastly, we believe that maintaining the same threshold and coinsurance rate from year-to-year will help promote stability and predictability for issuers.

As detailed further below, HHS established a new process, beginning with the 2020 benefit year, for states to request reductions in transfers calculated under the HHS state payment transfer formula.⁶⁸ This process was intended in part to aid smaller issuers that owed substantial risk adjustment charges that they did not anticipate.⁶⁹ However, HHS previously considered and otherwise declined to adopt a cap on risk adjustment charges.⁷⁰ We remain concerned that a general cap on risk adjustment transfers would reduce the necessary risk adjustment payments to issuers with higher-risk enrollees and undermine the risk adjustment program's effectiveness.⁷¹ More specifically, 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. 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. As described in a previous section of this rulemaking, we are continuing to consider future policy options to improve the predictability and accuracy of the risk adjustment models. Modifications that improve predictability and accuracy would ultimately help new and small issuers. We did not propose and are not finalizing exemptions for new issuers or the adoption of a creditability approach to participation in the HHS-operated risk adjustment program.

(1) State Flexibility Requests (§ 153.320(d))

In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology, which is calibrated on a national dataset, for the state's individual, small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's market(s). We finalized that any requests received would be published in the respective benefit year's proposed notice of benefit and payment parameters, and the supporting evidence would be made available for public comment.⁷²

⁶⁸ 83 FR at 16955.

⁶⁹ 83 FR at 16956.

⁷⁰ 81 FR at 94101.

⁷¹ *Ibid.*

⁷² 2019 Payment Notice Final Rule, 83 FR 16930 (April 17, 2018) and 45 CFR 153.320(d)(3).

As finalized in the 2020 Payment Notice, 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 Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will make available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence.⁷³

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

For the 2021 benefit year, HHS received a request to reduce risk adjustment transfers for the Alabama small group market by 50 percent. Alabama's request states that the presence of a dominant carrier in the small group market precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the risk adjustment payment issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2021 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 solicited comment on this request to reduce risk adjustment transfers in the Alabama small group market by 50 percent for the 2021 benefit year. The request and additional documentation submitted by Alabama are posted under the "State Flexibility Requests" heading at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html>.

Based on our review of the comments received and HHS's analysis of the request submitted by Alabama, HHS is granting Alabama's request to reduce transfers in the small group market by 50 percent for the 2021 benefit year. The following is a summary of the public

⁷³ See 45 CFR 153.320(d)(3).

⁶⁷ See, for example, 84 FR at 17466–17467 and 81 FR at 94080–94082.

comments we received on Alabama's 2021 state flexibility request.

Comment: Multiple commenters claimed that waivers diminish the effectiveness of the risk adjustment program, and recommend that states should implement their own risk adjustment programs instead of seeking state flexibility in the HHS-operated risk adjustment program.

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

We reviewed Alabama's supporting evidence regarding the state's unique small group market dynamics that it believes warrant an adjustment to the HHS calculated risk adjustment small group market transfers for the 2021 benefit year. Alabama state regulators noted they do not assert that the HHS formula is flawed, only that it results in imprecise results in Alabama's small group market 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 increase for payment issuers, consistent with § 153.320(d)(1)(iii).

We note that HHS reviewed the state's unredacted supporting analysis in evaluating Alabama's request, along with other plan-level data available to HHS. We found the supporting analysis submitted by Alabama to be sufficient for us to evaluate the market-specific circumstances validating Alabama's request.

We agree with Alabama's assessment that any necessary premium increase for issuers likely to receive reduced payments as a result of the requested reduction to risk adjustment transfers in the Alabama small group market for the 2021 benefit year would not exceed 1 percent. HHS has determined that the state has demonstrated the existence of relevant state-specific factors that warrant an adjustment to more precisely account for relative risk differences and that the adjustment would have a *de*

minimis effect. Therefore, we are approving Alabama's requested reduction under § 153.320(d)(4)(i)(B) based on the state regulators' identification of unique state-specific factors in the Alabama small group market and the supporting analysis of a *de minimis* effect of the reduction requested. The 50 percent reduction will be applied to the 2021 benefit year plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation above) for the Alabama small group market.

Comment: Several commenters asked HHS to consider a multi-year approval process as it could provide stability to state market risk pools seeking these flexibility requests.

Response: Our regulations currently provide a process for the annual review of requests by state regulators seeking a reduction to risk adjustment transfers in the state's individual catastrophic risk pool, individual non-catastrophic risk pool, small group market or a merged market.⁷⁴ Therefore, we review any requests received on an annual basis, and currently do not have a process by which a multi-year approval process could be evaluated. It is also unclear if a state would have the necessary information to be able to submit the required justification under § 153.320(d)(1)(iii) in support of a multi-year request (as opposed to a request focused only on one upcoming benefit year). However, we appreciate the comment and intend to consider whether multi-year approval processes are appropriate in the future, and would propose any changes to this process in future rulemaking.

Comment: A commenter suggested that when repeat waiver requests occur that data from years where such a waiver has already occurred that data from past years be released to the public for analysis.

Response: As explained in the 2020 Payment Notice, we are concerned that releasing unredacted information from state flexibility requests can reveal market conditions and issuers' private financial data.⁷⁵ We believe it is important to protect information that contains trade secrets or confidential commercial or financial information within the meaning of the HHS FOIA regulations at § 5.31(d) and therefore will not post information the state requests HHS not make publicly available because it contains such trade

secrets or confidential commercial or financial information. We note that the 2020 benefit year is the first year for which a state flexibility request was requested and approved (Alabama in the small group market) and we will publish more information, such as issuers' transfers amounts, and the state average factors, including premiums, in the permanent risk adjustment transfers summary report for the 2020 benefit year issued by June 30, 2021. As such, this report will reflect the reduced transfers in Alabama, and stakeholders will be able to assess the impact of the transfers reduction on transfers as a percent of state average premiums for Alabama's small group market. We further note that Alabama's request for the 2020 benefit year remains posted on the CMS website,⁷⁶ such that stakeholders could review it alongside the state's new request for the 2021 benefit year.

c. Risk Adjustment User Fee for 2021 Benefit Year (§ 153.610(f))

As noted above, if a state is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. For the 2021 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.⁷⁷ 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 specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

Our authority to operate risk adjustment on the state's behalf arises from sections 1321(c)(1) and 1343 of the PPACA. The authority to charge this user fee can be found under sections 1343, 1311(d)(5), and 1321(c)(1) of the PPACA, and under 31 U.S.C. 9701, which permits a Federal agency to establish a charge for a service provided by the agency. 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

⁷⁴ See 45 CFR 153.320(d)(3), requiring HHS to publish state requests in the applicable benefit year's notice of benefit and payment parameters rulemaking.

⁷⁵ See 84 FR at 248-249. Also see 84 FR at 17484-17485

⁷⁶ <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs>.

⁷⁷ See 78 FR at 15416-15417.

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 2020 Payment Notice, we calculated the Federal administrative expenses of operating the risk adjustment program for the 2020 benefit year to result in a risk adjustment user fee rate of \$0.18 per member per month (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 2021 benefit year, we used 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 annual 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 2021 benefit year.

In the proposed rule, we estimated that the total cost for HHS to operate the risk adjustment program on behalf of states for 2021 will be approximately \$50 million, and the risk adjustment user fee would be \$0.19 PMPM. We sought comments on the proposed risk adjustment user fee rate.

We received several comments in support of the proposed risk adjustment user fee rate, however, we are not finalizing the 2021 benefit year risk adjustment user fee amount as proposed. At the time of the proposed rule, we estimated the 2021 benefit year risk adjustment user fee using the best information available on costs, allocations, and enrollment projections. However, as explained below, in light of new information, we are finalizing the risk adjustment user fee amount of \$0.25 PMPM for the 2021 benefit year, which reflects our updated estimate of \$60

million in total costs for HHS to operate the 2021 benefit year risk adjustment program on behalf of states.

Based on our analysis of newly available data and further evaluation of eligible costs, we now expect estimated risk adjustment user fee costs for the 2021 benefit year to increase, resulting in total estimated costs of \$60 million for program operations for the 2021 benefit year. We periodically reexamine user fee eligible costs, and we reevaluated our allocation of risk adjustment costs after the publication of the proposed rule. HHS re-assessed contracts after the publication of the proposed rule to evaluate portions of contracts spent on risk adjustment program activities. As a result of this reexamination, we determined that additional costs were attributable to risk adjustment program operations. This includes costs related to information technology technical assistance and support, cloud computing, collections, payments, program support, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support activities.

Additionally, our analysis of interim 2019 benefit year risk adjustment data, which was not available prior to publication of the proposed rule, revealed enrollment in 2019 benefit year risk adjustment covered plans that were lower than previously estimated based on the billable member month enrollment observed for the prior benefit years. The combination of the decline in enrollment estimates and the increase in risk adjustment user fee eligible costs altered our estimates and projections of both costs and collections for the 2021 benefit year risk adjustment program, resulting in an increase to the risk adjustment user fee required to cover the estimated costs of operating the program from the amount proposed. We are therefore finalizing a risk adjustment user fee amount of \$0.25 PMPM for the 2021 benefit year, reflecting our updated estimate of \$60 million in total costs to operate the program on behalf of states for the 2021 benefit year and the estimated decline in enrollment in risk adjustment covered plans. We believe finalizing a risk adjustment user fee amount of \$0.25 PMPM for the 2021 benefit year is necessary to ensure the HHS-operated risk adjustment program is fully funded with no risk of a shortfall. We also note risk adjustment user fee collections are spent on risk adjustment user fee eligible costs only, and while we have not had significant funds remaining in prior years, any amount collected in

excess of those required to fund eligible activities would be spent on future years' eligible activities and considered in future risk adjustment user fee rate estimates.

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

We conduct RADV under §§ 153.630 and 153.350 in any state where HHS is operating risk adjustment on a state's behalf, which for the 2021 benefit year includes all 50 states and the District of Columbia. The purpose of 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. The RADV program 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 assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk.

RADV consists of an initial validation audit and a second validation audit. Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation auditor. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to 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. In the proposed rule, we set forth proposed amendments and clarifications to the RADV program that stemmed from issuer feedback and HHS's examination of results from the first 2 pilot years and first transfer adjustment year of the program.

The following is a summary of the general public comments received related to RADV. Additional comments related to the application of RADV results when HCC counts are low and the designation of a second pilot year for the data validation of prescription drugs are discussed later in this rule.

Comment: Many commenters urged HHS to implement certain policy options discussed in the "HHS Risk Adjustment Data Validation (HHS-

RADV) White Paper,”⁷⁸ published on December 6th, 2019, with some commenters requesting that white paper policy options be incorporated into this final rule or that separate rulemaking be initiated to enable these provisions to be effective for 2019 RADV. Some of the policy options frequently advocated for include policies related to: (1) The “payment cliff” effect that occurs in the current methodology, which results in some issuers with similar RADV findings experiencing different risk score and transfer adjustments; (2) negative failure rates; and (3) the interaction between risk adjustment HCC hierarchies and HCC failure rate groups in RADV. One commenter also asked that the initial validation audit sample size be varied based on issuer-specific parameters or prior RADV results. Another commenter wanted to ensure the proposals outlined in the 2019 HHS–RADV White Paper will not impact 2018 benefit year RADV.

We also received several comments encouraging HHS to modify RADV beyond options discussed in the white paper or in the proposed rule. These include subdividing the RADV process so that the individual and small group markets are each assessed separately; changing the materiality threshold criteria to a percentage of statewide premiums; using the current method for determining outliers, but basing adjustments on divergence from a state mean rather than a national mean; and applying additional scrutiny when issuers’ supplemental data is dominated by additional diagnoses rather than modified or deleted diagnoses.

Response: We appreciate these comments and recognize the desire for further changes to the RADV program requirements to improve their reliability and integrity, including implementation of policy options explored in the 2019 HHS–RADV White Paper. However, we did not include in the proposed rule any of the options explored in the 2019 HHS–RADV White Paper and are not finalizing any of those options in this final rule. As explained in the 2019 HHS–RADV White Paper, our goal was to outline and seek feedback on certain RADV issues to inform future policy development.

HHS is committed to ensuring the integrity and reliability of RADV. Although the options explored in the 2019 HHS–RADV White Paper and the additional modifications to RADV suggested by commenters are outside of the scope of this rule, we continue to

explore potential modifications to this program and will propose any such changes for future benefit years through rulemaking. In response to the comment, we note that we do not intend to pursue the options explored in the 2019 HHS–RADV White Paper for the 2018 benefit year of RADV.

Comment: One commenter urged HHS to adopt the HEDIS (Healthcare Effectiveness Data and Information Set) audit methodology for RADV, which would only require medical record review for supplemental codes that the plan pulls from medical records.

Response: We continue to seek ways to improve RADV for both accuracy and user experience, and will continue to examine approaches taken by other organizations when making updates to the RADV process for future benefit years. However, because the intent of RADV is to ensure the integrity of the risk adjustment program by validating all diagnoses to confirm the issuer’s actuarial risk in a given benefit year as measured by the risk adjustment program, we believe that RADV should include a sample of all diagnoses, and not simply be limited to supplemental diagnoses. Additionally, we note that the HEDIS audit methodology is a two-part process that is customized based on an organization’s informational systems, and we believe that the distributed data environment (that is, issuers’ EDGE servers) precludes the need for such customization. As such, we are maintaining our current overall approach for RADV, with the modifications detailed below that are finalized in this rule.

Comment: One commenter requested that HHS use our authority to mandate the submission of medical records by providers to initial validation auditors for the purposes of RADV.

Response: Under sections 1321 and 1343 of the PPACA, HHS has authority to regulate issuers of risk adjustment covered plans, but not providers. However, as explained in the 2019 Payment Notice, we appreciate that issuers could experience some level of difficulty retrieving medical records. As a result, we updated the RADV error estimation methodology, by adopting confidence intervals to identify outliers, to account for some level of variation and error in validating HCCs.⁷⁹ Only outlier issuers have their risk scores adjusted as a result of RADV for this reason. In addition, recognizing these challenges exist, we have taken steps to provide assistance to issuers with this process. For example, we developed a

memorandum⁸⁰ that issuers can use to assist in their efforts to obtain medical records from providers for the RADV program. The memo explains the background and purpose of the RADV program and can be sent to providers along with the issuer’s request for medical records. We will continue to explore other ways we may be able to help issuers encourage provider response to medical records requests and whether there are mechanisms that would enable us to differentiate between issuers who are outliers due to unverified diagnoses or bad data, and those who are outliers due to unresponsive providers during medical record retrieval.

a. Application of Risk Adjustment Data Validation Adjustments in Cases Where HCC Count is Low

In the 2019 Payment Notice, to avoid adjusting all issuers’ risk adjustment transfers for expected variation and error, we finalized a new methodology to evaluate material statistical deviation in data validation failure rates beginning with 2017 benefit year RADV.⁸¹ When an issuer’s failure rate within a group of HCCs materially deviates from the mean of the failure rate for that HCC group, we apply the difference between the mean group failure rate and the issuer’s calculated failure rate. If all failure rates in a state market risk pool do not materially deviate from the national mean failure rates, we do not apply any adjustments to issuers’ risk scores for that benefit year in the respective state market risk pool.⁸²

Consistent with the methodology finalized in the 2019 Payment Notice, for RADV for 2017 and 2018 benefit years, we calculate the data validation failure rate for each HCC in issuers’ initial validation audit samples as:

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

Where:

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

Freq_IVA^h is the frequency of HCC code *h* occurring in initial validation audit results, which is the number of sampled

⁸⁰ Available at https://www.regtap.info/uploads/library/2018_BY_HHS-RADV_Provider_Medical_Record_Request_Memo_073119_5CR_073119.pdf.

⁸¹ See 83 FR at 16961–16965.

⁸² When an issuer is determined to be an outlier in an HCC group, the transfers for other issuers in the state market risk pool (including those who are not outliers in any HCC group) will also be adjusted due to the budget neutral nature of the HHS-operated risk adjustment program.

⁷⁸ See <https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper>.

⁷⁹ See 83 FR at 16961–16965.

enrollees with HCC code *h* on in initial validation audit results.
 FR^h is the failure rate of HCC code *h*.

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

have an unequal number of unique HCCs, but the total observations in each group are approximately equal based on total observations of HCCs reflected in EDGE data for all issuers' initial validation audit sample enrollees.

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

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

Where:

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

$Freq_IVA_i^G$ is the number of HCCs in group *G* in the initial validation audit sample of issuer *i*.

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

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

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

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

Where:

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

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

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

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

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

Where:

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

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

When an issuer's HCC group failure rate is an outlier, we reduce (or increase) each of the applicable initial validation audit sample enrollees' HCC coefficients by the difference between the outlier issuer's failure rate for the

HCC group and the weighted mean failure rate for the HCC group. Specifically, this results in the sample enrollees' applicable HCC risk score components being reduced (or increased) by a partial value, or percentage, calculated as the difference between the outlier failure rate for the HCC group and the weighted mean failure rate for the applicable HCC group. The adjustment amount for outliers is the distance between issuer *i*'s Group Failure Rate GFR_i^G and the weighted mean $\mu(GFR^G)$, calculated as:

If $GFR_i^G > UB^G$ or $GFR_i^G < LB^G$:
 Then $Flag_i^G = \text{"outlier"}$ and $Adjustment_i^G = GFR_i^G - \mu(GFR^G)$

If $GFR_i^G \leq UB^G$ and $GFR_i^G \geq LB^G$:
 Then $Flag_i^G = \text{"not outlier"}$ and $Adjustment_i^G = 0$

Where:

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

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

We then compute total adjustments and risk adjustment transfer error rates for each issuer based on the sums of the $Adjustment_i^G$.⁸³

Although the failure rate and error estimation methodology described above is based on the number of HCCs within a sample, our sampling methodology samples individual enrollees and varies in size for issuers with fewer than 4,000 enrollees,⁸⁴ rather than sampling HCCs directly. This difference in unit of analysis between the error estimation methodology—which applies to all non-exempt RADV issuers, regardless of their size—and the sampling methodology may lead to fewer HCCs in an HCC group than are necessary to reliably determine whether an issuer is an outlier at the targeted precision and confidence levels—that is, whether an issuer is statistically different from the national (average) HCC failure rate, as defined by an unadjusted 95 percent confidence interval.

Standard statistical theorems⁸⁵ state that, as sample sizes increase, the

⁸⁴ For issuers with fewer than 4,000 enrollees, the sample size varies according to a finite population correction (FPC) such that $n_{adjusted} = n_{original} * FPC$, where $n_{adjusted}$ is the adjusted sample size and $n_{original}$ is the original sample size of 200 enrollees. The FPC is determined by the equation $FPC = (N - n_{original}) / N$, where *N* is the population size. By these formulae, if an issuer's adjusted sample size would be smaller than 50 enrollees, that issuer should sample either a minimum of 50 enrollees or their entire population of enrollees, whichever is smaller. See *Ibid* at 37.

⁸⁵ In other words, the Central Limit Theorem (CLT). For background regarding the CLT, see Ivo D. Dinov, Nicolas Christou, and Juana Sanchez.

⁸³ See, for example, the 2018 Benefit Year Protocols: PPACA HHS Risk Adjustment Data Validation, Version 7.0 (June 24, 2019) that are available at https://www.regtap.info/uploads/library/HRADV_2018Protocols_070319_5CR_070519.pdf.

sampling distribution of the means of those samples (in this case, the distribution of mean HCC group failure rates) will more closely approximate a normal distribution. Lower sample sizes are more likely to lead to non-normal distributions of sample summary statistics—for example, the means of multiple samples—if the distribution of the underlying population is non-normal. The divergence from a normally distributed distribution of sample means that can occur at lower sample sizes may result in violations of the assumptions of statistical testing, which may lead to the detection of more apparent outliers than would be desirable.

Taking all of these points into consideration, we conducted an analysis in which we simulated the selection of samples from an average issuer using progressively smaller HCC counts. By this process we identified that, if the number of HCCs per sample of enrollees was below 30 HCCs, the implied alpha of our statistical tests for outliers was higher than our 5 percent target, thereby failing to meet the threshold for statistical significance. Moreover, statistical practice often relies on a standard recommendation regarding the determination of sample size, which states that sample sizes below 30 observations are often insufficient to assume that the sampling distribution is normally distributed.⁸⁶

Based on these findings, we proposed to amend the outlier identification process and not consider as an outlier any issuer's failure rate for an HCC group in which that issuer has fewer than 30 HCCs beginning with 2019 benefit year RADV. Furthermore, we proposed that such issuers' data would continue to be included in the calculation of national metrics for that HCC group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer would not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarified that this issuer may be considered an outlier in other HCC groups in which it has 30 or more HCCs. Under the proposal, the adjustment amount for outliers would continue to be the distance between

issuer i 's Group Failure Rate GFR_i^G and the weighted mean $\mu(GFR^G)$ calculated as:

If $GFR_i^G > UB^G$ or $GFR_i^G < LB^G$,
 And if $Freq_EDGE_i^G \geq 30$:
 Then $Flag_i^G = \text{"outlier"}$ and $Adjustment_i^G = GFR_i^G - \mu(GFR^G)$
 If $GFR_i^G \leq UB^G$ and $GFR_i^G \geq LB^G$,
 Or if $Freq_EDGE_i^G < 30$:
 Then $Flag_i^G = \text{"not outlier"}$ and $Adjustment_i^G = 0$

We solicited comments on this proposal.

After consideration of comments, we are finalizing the policy as proposed such that beginning with 2019 benefit year RADV⁸⁷, we will not consider issuers with fewer than 30 HCCs in an HCC failure rate group to be outliers in that HCC failure rate group, but will continue to include such issuers in the calculation of national metrics. In addition, these issuers may still be considered outliers in other HCC groups in which they have 30 or more HCCs. The following is a summary of the public comments we received on this proposed policy.

Comment: All commenters that submitted comments on this topic supported the proposed modification to the outlier identification process to not consider issuers with fewer than 30 HCCs in an HCC failure rate group as outliers in RADV beginning with the 2019 benefit year.

Response: After consideration of comments, we are finalizing the policy as proposed such that beginning with 2019 benefit year RADV, we will not consider issuers with fewer than 30 HCCs in an HCC failure rate group to be outliers in that HCC failure rate group, but will continue to include such issuers in the calculation of national metrics. In addition, these issuers may still be considered outliers in other HCC groups in which they have 30 or more HCCs. We also generally remind issuers that when an issuer is determined to be outlier in an HCC group, the transfers for other issuers in the state market risk pool (including those who are not outliers) will also be adjusted due to the budget neutral nature of the HHS-operated risk adjustment program.

⁸⁷ As part of the Administration's efforts to combat the Coronavirus Disease 2019 (COVID-19), we recently announced the postponement of the 2019 benefit year RADV process. We intend to provide further guidance by August 2020 on our plans to begin 2019 benefit year RADV in calendar year 2021. See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

b. Prescription Drugs for the 2019 Benefit Year Risk Adjustment Data Validation

In the 2020 Payment Notice,⁸⁸ we finalized an approach to incorporate RXCs into RADV as a method of discovering materially incorrect EDGE server data submissions in a manner similar to how we address demographic and enrollment errors discovered during RADV. We also finalized an approach to pilot the incorporation of these drugs into the RADV process for 2018 benefit year RADV, and stated that RXC errors that we identified during the 2018 benefit year RADV RXC pilot will not be used to adjust risk scores or transfers. We stated that we finalized this policy to treat the incorporation of RXCs into 2018 benefit year RADV as a pilot year to allow HHS and issuers to gain experience in validating RXCs before RXCs are used to adjust issuers' risk scores.

Following continued analysis of the issue after publication of the 2020 Payment Notice, in the proposed rule, we proposed that the 2019 benefit year RADV would serve as a second pilot year for the purposes of prescription drug data validation, in addition to the 2018 benefit year RADV pilot for prescription drugs. The proposed second pilot year is consistent with the 2 pilot years provided for the 2015 and 2016 benefit years of the RADV program. We also noted in the proposed rule that the proposal was also responsive to issuer concerns that were previously expressed in comments to the 2020 Payment Notice.⁸⁹ We solicited comments on this proposal.

In light of the comments received, we are finalizing the proposal to treat the 2019 benefit year⁹⁰ as a second pilot year for RXC validation.

We summarize and respond to the public comments received below.

Comment: All stakeholders who commented on this proposal supported a second pilot year for RXC validation. Several commenters encouraged HHS to

⁸⁸ 84 FR 17454 at 17498 through 17503.

⁸⁹ See, for example, America's Health Insurance Plans comment on HHS Notice of Benefit and Payment Parameters for 2020 Proposed Rule, February 19, 2019, <https://www.regulations.gov/contentStreamer?documentId=CMS-2019-0006-23013&attachmentNumber=1&contentType=pdf>, and BlueCross BlueShield Association comment on HHS Notice of Benefit and Payment Parameters for 2020 Proposed Rule, February 19, 2019, <https://www.regulations.gov/contentStreamer?documentId=CMS-2019-0006-23345&attachmentNumber=1&contentType=pdf>.

⁹⁰ As noted above, we recently announced the postponement of the 2019 benefit year RADV process as part of the Administration's efforts to combat COVID-19. See, *supra* note 87 and <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

"Central limit theorem: New SOCR applet and demonstration activity." Journal of Statistics Education 16, no. 2 (2008). DOI: 10.1080/10691898.2008.11889560.

⁸⁶ For example, David C. Howell, "Hypothesis Tests Applied to Means" In *Statistical Methods for Psychology* (8th Ed.), 177–228. Belmont, CA: Wadsworth, 2010.

provide issuers with additional data and reports of the findings from the 2018 benefit year RADV RXC validation pilot.

Response: As explained in the proposed rule, we recognize that there may be more differences between validating HCCs and RXCs that need to be considered when incorporating RXCs into RADV than initially anticipated and that the metrics to validate a RXC are not the same as coding a HCC. A second pilot year for validation of RXCs provides additional time to examine these issues and any potential mitigating strategies (as may be necessary). Therefore, we are finalizing a second pilot year (2019 benefit year) for RXC validation to give HHS and issuers more time and experience with the prescription drug data validation process before those results will be used to adjust risk scores and transfers. Additionally, we intend to provide issuers with additional data and analysis from the 2018 benefit year RADV prescription drug data validation pilot when we release our 2018 benefit year RADV error rate results memo in May 2020.

Comment: One commenter recommended that HHS include the drug name in the National Drug Code (“NDC”) to RXC mapping because they believed that not all the NDCs in the RXC model are listed in the Federal Drug Administration’s drug inventory.

Response: We refer the commenter to the most recent HHS-Development Risk Adjustment Model Algorithm “Do It Yourself (DIY)” Software,⁹¹ which contains all NDCs that were active at any point during the benefit year to which the DIY software refers and that crosswalk to RXCs. Some of the Federal Drug Administration’s drug reference sources use 10-digit NDC codes, but the DIY Software uses 11-digit NDC codes. Drug names can be identified from the 11-digit NDC code via the National Institutes of Health’s RxNorm system.⁹² Some of the NDCs in the DIY Software may be marked with an obsolete status in the RxNorm system; however, all NDCs are referenced against the EDGE NDC Global Reference List for active status at the time of the claim.

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

1. Verification Process Related To Eligibility for Insurance Affordability Programs

a. Employer-Sponsored Plan Verification

We proposed that HHS would not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), when the Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), for plan years 2020 and 2021. We also proposed that HHS would exercise such discretion in anticipation of receiving the results of the employer verification study described in the proposed rule. We are finalizing this policy as proposed.

Strengthening program integrity with respect to subsidy payments in the individual market continues to be a top priority. Currently, Exchanges must verify whether an applicant is eligible for or enrolled in an eligible employer-sponsored plan for the benefit year for which coverage is requested using available data sources, if applicable, as described in § 155.320(d). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), an alternate procedure is required. Specifically, Exchanges must select a statistically significant random sample of applicants and meet the requirements of § 155.320(d)(4)(i). We discussed in the proposed rule that we are exploring a new alternative approach to replace the current procedures in § 155.320(d)(4)(i), under which an Exchange may design its verification process based on the Exchange’s assessment of risk for inappropriate eligibility or payment for 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 sampled enrollees have been determined by HHS to have received APTC/CSRs inappropriately. We discussed in the proposed rule that we believe an approach to verifying an applicant’s attestation regarding access to an employer-sponsored plan 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 § 155.320(d)(4)(i), HHS questioned whether this methodology was the best approach for all Exchanges to assess the associated risk for inappropriate payment of APTC/CSRs. As such, 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 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. The results of this study, which HHS expects to be finalized sometime in 2020, will inform the approach we would propose in future rulemaking to allow Exchanges to design an employer-sponsored coverage verification based upon their assessment of the risk of potential inappropriate payments of APTC/CSRs to those with offers of affordable employer-sponsored coverage for Exchanges using the Federal eligibility and enrollment platform. HHS also encouraged State Exchanges to conduct similar research of their past and current enrolled populations in anticipation of this future rulemaking.

As HHS continues to explore the best options for verification of employer-sponsored coverage, we proposed that HHS would not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), as an alternative to performing this verification against the data sources required under § 155.320(d)(2)(i) through (iii), for plan years 2020 and 2021. We also proposed that HHS would exercise such discretion in anticipation of receiving the results of the employer verification study described in the proposed rule.

Comment: All 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

⁹¹ See <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index>.

⁹² See <https://www.nlm.nih.gov/research/umls/rxnorm/index.html>.

verification processes that are evidence-based, while imposing the least amount of burden on consumers, states, employers, and taxpayers. One commenter supported the proposal, but sought clarification on whether the non-enforcement policy would apply to State Exchanges with corrective active plans currently under § 155.320(d)(4). Another commenter suggested that HHS make available a reliable data source for verification of employer-sponsored coverage.

A commenter suggested that, as HHS reviews the results of the study discussed in the preamble to the proposed rule, we should consider that soliciting additional information from employers and plan sponsors regarding employer-sponsored coverage through the random sampling process under § 155.320(d)(4) is not necessary because this information regarding employer-sponsored coverage for employees is already provided annually on Internal Revenue Service (IRS) Form 1095-C, Employer-Provided Health Insurance Offer and Coverage.

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. HHS will also continue to explore the availability of other data sources that may be used to verify offers of employer-sponsored coverage, such as the National Directory of New Hires (NDNH), however, access to that database would require statutory changes. Finally, we agree that as HHS reviews the results of the study discussed earlier in this preamble, we should also continue to explore whether there may be information that applicable large employers can provide regarding coverage available to employees as we generally agree with the premise that HHS should avoid soliciting duplicative information, if possible. We note however that Forms 1095-C would have limited utility in

helping an Exchange to verify a current offer of employer-sponsored coverage because they are provided to employees after a coverage year has ended.

In response to comments on the proposed non-enforcement policy, we clarify that the non-enforcement of the requirement to conduct the random sampling process under § 155.320(d)(4)(i) will apply for plan years 2020 and 2021 to all State Exchanges, including those that currently have existing corrective action plans under which the State Exchange proposed to implement the random sampling process required under § 155.320(d)(4)(i) as an alternative to conducting this verification using the data sources under § 155.320(d)(2).

HHS further reminds State Exchanges that they 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 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: One commenter also supported the proposal, but suggested that HHS consider reinstating timely notices from the Exchanges using the Federal platform to employers, required under § 155.310(h) and referenced at § 155.320(d)(4)(i)(E), regarding employees who are receiving APTC/CSRs.

Response: We did not propose policies or requirements related to employer notices under § 155.310(h) or elsewhere, and this comment is outside the scope of this rulemaking. However, we wish to clarify that there are limitations on the extent to which notification to employers regarding employees who are receiving APTC/CSRs under § 155.310(h) would alleviate the difficulties that employers may face with regard to the assessment of employer shared responsibility payments (ESRPs) in section 4980H of the Code. Based on HHS's experience with the Exchanges issuing such notices to employers, the Exchange does not

have the capability to distinguish between employers that are or are not subject to the ESRP. In addition, HHS found that these notices caused substantial confusion among employers, as many employers interpreted the notices as an assessment of the ESRP. HHS also believes that while these notices could offer employers the opportunity to dispute an employee's eligibility for APTC/CSRs, the outcome of such a dispute may have no impact on the IRS's assessment of the ESRP. IRS's assessment of the ESRP and whether an employer is liable for the ESRP, is solely within the purview of the IRS. Therefore, HHS believes that the notice and dispute processes authorized for Exchanges would not contribute positively to verifying whether employees have affordable offers of employer sponsored coverage that meet minimum value. Furthermore, per § 155.310(i), the IRS currently sends letters to employers, known as "226-J letters," to certify to an employer that one or more employees has enrolled for one or more months during a year in a QHP with APTC in order to satisfy the requirement under section 4980H of the Code.

After reviewing the public comments, we are finalizing this proposal as proposed.

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

a. Process for Voluntary Termination Upon a Finding of Dual Enrollment via Periodic Data Matching (PDM)

We proposed to amend § 155.330(e)(2)(i)(D) to provide that Exchanges need not redetermine eligibility for APTC or CSRs for enrollees who (1) are found to be dually enrolled in QHP coverage and MEC consisting of Medicare, Medicaid/CHIP, or, if applicable, the Basic Health Program (BHP); (2) have not responded to the Exchange notice to provide updated information within 30-days; and (3) have previously provided written consent for the Exchange to end their QHP coverage via PDM in the event of dual enrollment or eligibility. We are finalizing these amendments as proposed.

In accordance with § 155.330(d)(3), Exchanges must periodically examine available data sources (beginning with the 2021 calendar year, generally at least twice per calendar year) to determine whether enrollees in a QHP through an Exchange who are receiving APTC or CSRs have been determined eligible for or are enrolled in other qualifying coverage through Medicare, Medicaid, CHIP, or the BHP, if a BHP is operating

in the service area of the Exchange. Individuals enrolled in one of these forms of MEC and Exchange coverage are referred to as ‘dually-enrolled’ consumers and are identified through periodic data matching against government and commercial sources, known as periodic data matching or PDM.

Section 155.430(b)(1)(ii) requires an Exchange to provide an opportunity at the time of plan selection for an enrollee to choose to remain enrolled in QHP coverage or have their QHP coverage terminated if the Exchange finds that he or she has become eligible for or enrolled in other MEC, or to terminate QHP coverage if the enrollee does not choose to remain enrolled in the QHP upon completion of the redetermination process. As such, for plan year 2018 and thereafter, HHS added language to the single streamlined application generally used by the Exchanges using the Federal platform to allow consumers to authorize the Exchange to obtain eligibility and enrollment data and, if so desired by the consumer, to end their QHP coverage if the Exchange finds during PDM that the consumer has become eligible for or enrolled in other MEC. A consumer’s authorization for the Exchange to end QHP coverage is voluntary, as consumers may opt-in to or opt-out of permitting the Exchange to process a voluntary termination of QHP coverage if the consumers are found to be also enrolled in other MEC, via PDM. We note that the PDM operational processes described above pertain only to those Exchange enrollees receiving APTC/CSRs in accordance with § 155.330(d)(ii).

We further noted that for plan year 2019 and beyond, the Exchanges using the Federal platform will continue to end QHP coverage or subsidies for Medicare PDM only; terminations of Exchange coverage based on consumer pre-authorization resulting from Medicaid/CHIP PDM will be implemented at a time deemed appropriate by HHS to ensure the accuracy of the Medicaid/CHIP data before it is utilized for Exchange coverage terminations. Additionally, because the Medicaid/CHIP population may become eligible or ineligible for Medicaid/CHIP throughout a plan year as eligibility for the program is directly tied to fluctuations in income, we discussed that HHS will continue to evaluate the best manner by which to implement this process for Medicaid/CHIP PDM to ensure that Exchange enrollees do not experience unnecessary gaps in coverage. Similarly, we suggested that the two State Exchanges that operate their own eligibility and

enrollment platform and that currently offer BHP coverage—New York and Minnesota—consider adding the option for consumer pre-authorization of terminations of Exchange coverage resulting from BHP PDM.

Given that enrollees may permit the Exchanges to terminate their QHP enrollment upon finding that they are dually-eligible for or enrolled in other MEC, in accordance with § 155.330(d), discussed above, we proposed to amend § 155.330(e)(2)(i)(D) to provide that Exchanges need not redetermine eligibility for APTC or CSRs for enrollees who (1) are found to be dually enrolled in QHP coverage and MEC consisting of Medicare, Medicaid/CHIP, or, if applicable, the BHP, (2) have not responded to the Exchange notice to provide updated information within 30 days, as required by § 155.330(e)(2)(i), and (3) have provided written consent to the Exchange to act to end their QHP coverage via PDM in the event of dual enrollment or eligibility. We discussed in the proposed rule that we believe that the revision would ensure more efficient Exchange operations and would make clear that a voluntary QHP termination conducted as part of PDM under § 155.430(b)(1)(ii) follows the same process as other enrollee-initiated voluntary terminations of QHP coverage. Furthermore, we noted that we believe the changes would support HHS’s program integrity efforts by helping to ensure that APTC or CSRs are not paid inappropriately to those enrollees who are ineligible to receive subsidies. Finally, we stated that we believe the change would also ensure more efficient termination of unnecessary or duplicative coverage for consumers who have opted to have their coverage terminated in such circumstances.

We solicited comment on this proposal.

Comment: We received multiple comments in support of PDM as an effort to improve Exchange program integrity. These commenters agreed that the process has a positive impact on consumers as it helps inform Exchange enrollees of their enrollment in potentially duplicative other MEC, such as certain Medicare and Medicaid coverage, CHIP, or, if applicable, the BHP. Commenters also noted that the proposed changes help support efficient Exchange operations with respect to the PDM process, while minimizing burden on stakeholders such as states, issuers, consumers, and taxpayers. Commenters appreciated that the proposed changes continue to support flexibility for State Exchanges by providing all Exchanges with the option to allow applicants to

provide written consent for Exchanges to end their QHP coverage if later found to be enrolled in Medicare, Medicaid/CHIP, or, if applicable, the BHP. A few commenters supported the proposed changes but sought clarification regarding whether eligibility determinations for APTC/CSRs would still be completed for non-impacted members remaining on the application. A few commenters suggested improvements that could be made to current PDM processes or noted concerns for HHS to consider.

We also received some mixed comments that supported the overall PDM process but cautioned us regarding the impact these proposed changes could have for the Medicaid/CHIP population. Commenters urged HHS to exercise caution as to not create coverage gaps for this population while other comments argued that terminations of QHP coverage through the Medicaid/CHIP process is inconsistent with current PDM requirements under § 155.330(d). One commenter suggested that we revise the current application question where applicants can provide written consent for Exchanges to end their QHP coverage through PDM to exclude Medicaid/CHIP as this language could be confusing for consumers as Exchanges currently do not terminate QHP coverage through Medicaid/CHIP PDM.

Response: We agree with commenters that the PDM process is an important tool for Exchange program integrity. We also agree with commenters that the PDM process helps inform consumers of their enrollment in potentially duplicative other MEC such as certain Medicare and Medicaid coverage, CHIP, or BHP, and helps consumers avoid a tax liability for having to repay APTC received during months of overlapping coverage when reconciling at the time of annual federal income tax filing.

Under current Medicare PDM operations in the Exchanges that use the Federal platform, when enrollees on whose behalf APTC or CSRs are being provided are identified as being enrolled in both an Exchange QHP and in Medicare (dual enrollment), notices are sent to the household contact, who may not always be the Medicare dual enrollee. The notice includes a list of persons on the household contact’s Exchange application that the Exchange has identified as dually enrolled in Exchange coverage and Medicare. Enrollees have 30 days to respond to the Medicare PDM notice before the Exchange takes action to either end APTC/CSRs or QHP coverage for the Medicare dual enrollee. For non-dual

enrollees remaining on the application, to the extent they are eligible to continue their coverage, the Exchange will redetermine their eligibility for APTC/CSRs, and their coverage will continue with the APTC/CSR adjusted, as applicable. The same is true for Medicare dual enrollees who do not provide written consent for the Exchange to end their QHP coverage. In these cases, the Medicare dual enrollee is no longer eligible for APTC/CSRs, and eligibility is redetermined for the remaining persons on the application. Furthermore, in both scenarios, non-dual enrollees will receive an eligibility determination notice reflecting any changes to their eligibility for APTC/CSRs. In cases where family members of dual enrollees lose their coverage or their financial subsidies as a result of the PDM process described here, a special enrollment period may be available.

We appreciate commenters' concerns regarding QHP terminations for the Medicaid/CHIP population through PDM. We share these concerns and are exploring ways to implement terminations of QHP coverage for the Medicaid/CHIP population and to reduce consumer confusion. For example, in 2019, we revised the current application question by which applicants may provide written consent for the Exchange to terminate their QHP coverage through PDM to ensure that consumers understand the consequences of dual enrollment. HHS is also currently exploring ways to operationalize terminations through Medicaid/CHIP PDM that are the least disruptive for Medicaid/CHIP dual enrollees, as eligibility for Medicaid/CHIP may change throughout a plan year due to fluctuations in household income. We want to ensure that terminations through Medicaid/CHIP PDM are developed in a manner that still provides a pathway back into QHP coverage should a previously identified Medicaid/CHIP dual enrollee no longer be eligible for Medicaid/CHIP and need to be re-enrolled in an Exchange QHP. We are also exploring ways to improve the accuracy of state Medicaid/CHIP data to ensure that Exchange enrollees are not erroneously identified as also enrolled in Medicaid/CHIP and subsequently lose Exchange QHP coverage due to data errors. We continue to monitor data matching results each round of Medicaid/CHIP PDM and are working to provide guidance directly to states in instances where we believe data matching errors may have occurred.

Finally, we disagree with commenters that terminations of Exchange QHP

coverage through Medicaid/CHIP PDM is inconsistent with the current regulation at § 155.330(d). As discussed in the preamble, the Exchange has authority under § 155.430(b)(1)(ii) to provide the opportunity for an enrollee to have their QHP coverage terminated if the Exchange finds that they have become eligible for or enrolled in other MEC, such as Medicare, Medicaid/CHIP, or, if applicable, the BHP. We believe that such terminations through PDM benefit consumers because they mitigate the risk that consumers are paying for duplicate coverage and the risk that consumers will be required to pay back all or some of the APTC received during months of overlapping coverage.

After reviewing the public comments, we are finalizing the proposal as proposed.

b. Effective Date for Termination via Death PDM

In accordance with § 155.330(e)(2), Exchanges must periodically check available data sources to identify Exchange enrollees who are deceased and must terminate a deceased person's QHP coverage after following the process outlined at § 155.330(e)(2)(i) and after a redetermination of eligibility in accordance with § 155.330(e)(1). We proposed to amend § 155.330 to allow Exchanges, under appropriate circumstances, to terminate a deceased enrollee's coverage retroactively to the date of death, with no requirement to redetermine the eligibility of the deceased enrollee. We are finalizing this amendment as proposed.

In 2019, Exchanges using the Federal platform conducted one check for enrollees who are enrolled in QHP coverage and may have become deceased during plan year 2019. For plan year 2019 and beyond, under § 155.430(d)(7), Exchanges currently must terminate QHP coverage retroactively to the date of death when the Exchange terminates coverage due to the death of an enrollee during a plan year. We proposed to further amend § 155.330(e)(2)(i)(D) to provide that Exchanges are not required to redetermine eligibility of a deceased enrollee when the Exchange identifies a deceased enrollee via PDM and the enrollee does not respond or contest the updated information within the 30-day period specified in paragraph (e)(2)(i)(B). Under such circumstances, the Exchange would terminate coverage retroactively to the date of death, as specified in § 155.430(d)(7), with no requirement to redetermine the eligibility of the deceased enrollee. We explained in the proposed rule that we believe this policy will strengthen the

integrity of the individual market by mitigating the risk of unnecessary funds leaving the Treasury in the form of APTC or CSRs for enrollees identified as deceased during a plan year.

We solicited comment on this proposal.

Comment: All commenters that submitted comments on this topic supported our proposal that Exchanges terminate coverage retroactively to the date of death without redetermining the eligibility of the deceased enrollee as part of PDM. These commenters noted that this proposal will support the expeditious termination of deceased enrollees and will be helpful to the families of the deceased enrollee, resulting in a positive consumer experience.

Response: We agree that the PDM process is an important tool to identify Exchange enrollees who may have become deceased during a plan year to ensure that issuers do not receive financial assistance on behalf of deceased enrollees and that deceased enrollees are more timely removed from QHP coverage. As commenters noted, the death of a family member or friend is a stressful time and those impacted may delay or forget to end QHP coverage for the deceased enrollee. In these instances, we agree that PDM can play an important role for the families of deceased enrollees by taking action to terminate QHP coverage for the deceased enrollee.

Comment: One commenter suggested that as part of PDM operations to identify deceased enrollees during a plan year, HHS should provide issuers with a specific reason code that identifies QHP plan terminations due to death.

Response: No additional reason code is necessary to identify QHP plan terminations due to death. In 2019, Exchanges using the federal eligibility and enrollment platform began conducting periodic checks for deceased enrollees on single member applications and subsequently terminated the deceased enrollee's QHP coverage back to the date of death. In order to notify issuers of these changes, we developed new maintenance reason codes specific to deceased enrollees discovered through PDM that issuers may use to identify Exchange enrollees who were terminated due to death. Exchange issuers receive these PDM specific maintenance reason codes through the 834 transaction process.

We are finalizing this policy as proposed, to amend § 155.330(e)(2)(i)(D) to reflect that Exchanges must terminate coverage retroactively back to the date of death in accordance with

§ 155.430(d)(7), with no requirement to redetermine eligibility for the deceased enrollee.

3. Automatic Re-Enrollment Process

In the proposed rule, we solicited comment on whether we should modify the automatic re-enrollment process such that any enrollee who would be automatically re-enrolled with APTC that would cover the enrollee's entire premium would instead be automatically re-enrolled without APTC or with some lesser amount of APTC. We are not finalizing changes to the automatic re-enrollment process in this rule.

In the proposed rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020" (84 FR 227) (proposed 2020 Payment Notice) we explained that enrollees in plans offered through Exchanges using the Federal platform can take action to re-enroll in their current plan or to select a new plan, or they can take no action and be automatically re-enrolled in their current plan (or if their current plan is no longer available, a plan selected under a hierarchy designed to identify a plan that is similar to their current plan).

Since the Exchange program's inception, Exchanges using the Federal platform have maintained an automatic re-enrollment process which generally continues enrollment for enrollees who do not take action to actively select the same or a different plan. Automatic re-enrollment significantly reduces issuer administrative expenses, makes enrolling in health insurance more convenient for the consumer, and is consistent with general health insurance industry practice. In the open enrollment period for 2019 coverage, 1.8 million people in FFE and SBE-FP states were automatically re-enrolled in coverage, including about 270,000 persons who were enrolled in a plan with zero premium after application of APTC.

The proposed 2020 Payment Notice sought comment on automatic re-enrollment processes and capabilities, as well as additional policies or program measures that might reduce eligibility errors and potential government misspending. As we noted in the final rule, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020" (84 FR 17454) (final 2020 Payment Notice), commenters unanimously supported retaining the automatic re-enrollment processes. Supporters cited benefits such as the stabilization of the risk pool due to the retention of lower-risk

enrollees who are least likely to actively re-enroll, the increased efficiencies and reduced administrative costs for issuers, the reduction of the numbers of uninsured, and lower premiums. Commenters believed existing processes, such as eligibility redeterminations, electronic and document-based verification of eligibility information, PDM, and APTC reconciliations, are sufficient safeguards against potential eligibility errors and increased federal spending.

We also noted in the final 2020 Payment Notice that we would continue to explore options to improve Exchange program integrity. As such, in the proposed 2021 Payment Notice, we solicited comment on modifying the automatic re-enrollment process such that any enrollee who would be automatically re-enrolled with APTC that would cover the enrollee's entire premium would instead be automatically re-enrolled without APTC or with a lesser amount of APTC. This modification could address concerns that automatic re-enrollment may lead to incorrect expenditures of APTC, some of which cannot be recovered through the reconciliation process due to statutory caps. We considered that there may be particular risk associated with enrollees who are automatically re-enrolled with APTC that cover the entire plan premium, since such enrollees do not need to make payments to continue coverage. The modifications discussed in the proposed rule could help ensure a consumer's active involvement in their re-enrollment because the consumer would need to return to the Exchange and obtain an updated eligibility determination prior to having the full amount of APTC for which the consumer was eligible paid to an issuer on their behalf for the upcoming year.

We further discussed in the proposed rule that if APTC for this population is reduced to a level that would result in an enrollee premium that is greater than zero dollars, the process would ensure a consumer's active involvement in re-enrollment because any enrollment in a plan with a premium greater than zero would require the enrollee to take action by making the premium payment to effectuate or maintain coverage and avoid termination of coverage for non-payment. We stated in the proposed rule that if we were to implement such a change, we would conduct consumer outreach and education alerting consumers to the new process and emphasizing the importance of returning to the Exchange during open enrollment to update their applications to ensure that their income and other

information is correct and that they are still in the best plan for their needs. This outreach could include fact sheets, email or mail outreach depending on preference, and education among issuers, agents, brokers, Navigators, and other assisters.

We noted that under current regulations at § 155.335, each Exchange has some flexibility to define its own annual redetermination procedures. We solicited comment on whether the approaches discussed above should be adopted, and whether they should be adopted only for Exchanges using the Federal platform, maintaining automatic re-enrollment flexibility for State Exchanges that operate their own eligibility and enrollment platforms.

On December 20, 2019, section 1311(c) of PPACA was amended to require the Secretary to establish a process to re-enroll persons enrolled in 2020 QHP coverage through an FFE who do not actively re-enroll for plan year 2021 and who do not elect to disenroll for 2021 coverage during the open enrollment period for 2021.⁹³ We believe the current automatic re-enrollment process under § 155.335(j) (that was in place during the 2020 open enrollment period and prior years) will satisfy this requirement for automatic re-enrollment for the 2021 plan year.

Comment: All but one commenters on this request for comments opposed modifying the current automatic re-enrollment processes for a variety of reasons. Many believed that adopting the proposed changes could disadvantage the lowest income group of Exchange enrollees by taking away financial assistance for which they are eligible without evidence that they are at greater risk of incurring overpayments of APTC. Others questioned HHS's legal authority to apply an amount of APTC other than that determined in accordance with section 36B of the Code and sections 1411 and 1412 of the PPACA. Some commenters were specifically opposed to any requirement that State Exchanges modify their automatic re-enrollment processes because it would require costly IT system reconfigurations, consumer noticing changes, and additional investments to support increased Exchange customer service capacity that would be necessary to address consumer confusion caused by the change.

Most commenters supported the current automatic re-enrollment

⁹³ Further Consolidated Appropriations Act, 2020, Division N, title I, subtitle F, section 608 (Pub. L. 116-94; December 20, 2019, enacting H.R. 1865).

process, citing benefits such as the stabilization of the risk pool due to the retention of lower risk enrollees who are least likely to actively re-enroll, the increased efficiencies and reduced administrative costs for issuers, the reduction of the numbers of uninsured, lower premiums, and promotion of continuity of coverage. Many commenters believed that existing processes, including annual eligibility redetermination, periodic data matching, and APTC reconciliation, sufficiently safeguard against potential eligibility errors and increased federal spending. Other commenters noted that HHS provided no data indicating that the groups targeted by the proposed modifications are at a higher risk of receiving APTC overpayments.

Response: In light of commenters' overwhelming opposition to changing our automatic re-enrollment process, we will not change the current process at this time. We believe that existing Exchange safeguards have mitigated the risk of inappropriate APTC payments. These safeguards include requiring checks of the most recent IRS data and APTC reconciliation on the annual federal income tax return. HHS put into place new 'Failure to Reconcile' checks in 2018 that discontinued access to APTC for enrollees who did not file an annual federal income tax return or who filed an annual federal income tax return, but did not reconcile APTC. In addition, recent changes made in the 2019 Program Integrity rule require all Exchanges to conduct period data matching at least twice per year. We appreciate the comments on current processes and we will continue to explore options to improve Exchange program integrity going forward.

Comment: One commenter supported the changes for which HHS solicited comment and suggested HHS should end automatic re-enrollment for all consumers who are eligible for APTC. The commenter stated that requiring consumers who are eligible for APTC to return to the Exchange each year will better ensure integrity of government spending on APTC, citing concerns around insufficient verifications processes.

Response: We appreciate this comment. Notwithstanding, given the concerns many commenters expressed and the safeguards we have implemented to ensure eligibility is verified, we believe it would be inappropriate to end automatic re-enrollment for all consumers who are eligible for APTC at this time. We will continue to monitor the effectiveness of current program integrity safeguards

and explore options to strengthen them in future rulemaking.

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

We proposed revisions to binder payment deadlines under § 155.400(e)(1)(i) through (iv) to ensure consistency with revisions we proposed to § 155.420. Specifically, we proposed that in the Exchanges using the Federal platform, special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection. We also proposed to align the retroactive effective date and binder payment rules so that any consumer who is eligible to receive retroactive coverage, whether due to a special enrollment period, a favorable eligibility appeal decision, or a special enrollment period verification processing delay, has the option to pay the premium due for all months of retroactive coverage through the first prospective month of coverage, or only the premium for 1 month of coverage and receive prospective coverage only. We are finalizing these revisions as proposed. For a full discussion of the proposals related to prospective binder payment rules at § 155.400(e)(1)(i) and (ii), and retroactive binder payment rules at § 155.400(e)(1)(iii) and (iv), please see the preamble to § 155.420 of the proposed rule.

5. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for Cost-Sharing Reductions

We proposed to revise § 155.420 to allow silver level QHP enrollees and their dependents who become newly ineligible for CSRs to change to a QHP that is one metal level higher or lower than their current plan. We are finalizing these revisions as proposed, except that we are delaying the effective date of the revision related to new plans that may be chosen by an enrollee who loses CSR eligibility.

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would move forward with a pre-enrollment verification of eligibility for certain special enrollment periods in all states served by the Federal platform. This practice was part of an effort to stabilize the individual market, and to address concerns that allowing individuals to enroll in coverage through a special enrollment period without electronic or document-based verification of eligibility could negatively affect the individual market risk pool by allowing individuals to

newly enroll in coverage based on health needs during the coverage year, as opposed to enrolling during open enrollment and maintaining coverage for a full year.

To address related concerns that Exchange enrollees were utilizing special enrollment periods to change plan metal levels due to health needs during the coverage year, which negatively affects the individual market risk pool, the Market Stabilization Rule also 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.⁹⁴

We proposed to amend these rules in order to allow enrollees and their dependents who become newly ineligible for CSRs while enrolled in a silver-level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment in an Exchange. Generally, § 155.420(a)(4) provides that enrollees who newly add a dependent through most types of special enrollment periods may add the dependent to their current QHP or enroll the dependent in a separate QHP,⁹⁵ 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). To ensure that individuals who are newly eligible for CSRs can access this benefit, § 155.420(a)(4)(ii) provides that if an enrollee and his or her dependents become newly eligible for CSRs in accordance with paragraph § 155.420(d)(6)(i) or (ii) and are not enrolled in a silver-level QHP, the Exchange must allow them to change to

⁹⁴ 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 §§ 155.420(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. See also the proposals about applicability of plan category limitations to certain special enrollment periods in this section of this final rule.

⁹⁵ Section 155.420(a)(4)(i) and (a)(4)(iii)(B) also provide that alternatively, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in 45 CFR 156.140(b).

a silver-level QHP so that they may access CSRs for which they are eligible.

However, as discussed in the proposed rule, there was no corresponding provision to permit enrollees and their dependents who become newly ineligible for CSRs in accordance with § 155.420(d)(6)(i) or (ii), and who are enrolled in a silver-level QHP, to change to a QHP of a different metal level in order to account for their change in financial assistance. Instead, if they wish to change plans, § 155.420(a)(4)(iii)(A) currently limits them to changing to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available). As explained in the proposed rule, since the implementation of § 155.420(a)(4) in states served by the Federal platform, HHS has received questions and concerns about this issue from Navigators, agents and brokers, and other enrollment assisters. Based on their experiences, consumers who lose eligibility for CSRs are often unable to afford cost sharing for their current silver-level QHP, and therefore, may need to change to a lower-cost QHP in order to maintain their coverage.

We proposed to redesignate § 155.420(a)(4)(ii) as (a)(4)(ii)(A) and add a new § 155.420(a)(4)(ii)(B) in order to allow enrollees and their dependents who become newly ineligible for CSRs in accordance with paragraph (d)(6)(i) or (ii) of this section, and are enrolled in a silver-level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment in an Exchange. We further proposed to modify § 155.420(a)(4)(iii) to include § 155.420(d)(6)(i) and (ii) for becoming newly ineligible for CSRs in the list of trigger events excepted from the limitations at § 155.420(a)(3)(iii). As discussed, the proposal may help affected 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. For example, an enrollee affected by an increase to his or her monthly premium payment could change to a bronze-level plan, while an enrollee who has concerns about higher copayment or co-insurance cost-sharing requirements could change to a gold-level plan. Finally, current regulations at 45 CFR 147.104(b)(2)(iii) establish that plan category limitations do not apply off-Exchange. Therefore, in the case of an individual who loses eligibility for CSRs and wishes to use his or her special enrollment period to purchase coverage off-Exchange, he or she is not limited to any specific metal level(s) of coverage.

We solicited comments on these proposals.

Comment: No commenters opposed this proposed change, and many commenters supported it for the reasons described above, explaining that allowing enrollees the flexibility to change to a plan of a different metal level based on a change in their financial assistance would allow more individuals to maintain coverage. Several commenters suggested that we provide more flexibility for Exchange enrollees to change to a different metal level plan. One commenter suggested allowing enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP to change to a QHP of any metal level. Another commenter suggested that enrollees who lose eligibility for APTC during the plan year should also be able to change to a plan of a different metal level. Several commenters disagreed with the need for plan category limitations in general. Of these commenters, one asked that State Exchanges have the option not to implement plan category limitations requirements at all. Another commenter noted that any loosening of special enrollment period regulations can affect the level of adverse selection in the market.

Response: We are finalizing these changes as proposed, but delaying to January 2022 the effective date for the modification of plan category limitations to allow Exchanges more time to implement the change. We agree with commenters who stated that it will help enrollees and their dependents who lose eligibility for CSRs during the plan year to stay enrolled in coverage by switching to a new QHP that better suits their changed financial situation. We disagree with commenters who suggested that the plan category limitation policy is not necessary to prevent adverse selection and protect the individual market risk pool. However, we acknowledge that enrollees who experience changes in their financial situation, such as an increase in income that makes them ineligible for APTC, may wish to change to a different metal level QHP for reasons that are not health related. Nonetheless, we share concerns that incorporating additional flexibility into plan category limitations rules could increase the risk of adverse selection; therefore, we are not doing so at this time.

Comment: While supporting this proposal in general, several commenters raised concerns 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.

Response: HHS acknowledges these concerns, and works to promote health insurance literacy including an understanding of the implications of changing plans mid-coverage year.

Comment: One commenter asked that HHS permit and encourage or require issuers to preserve progress towards a deductible and other accumulators for enrollees who switch to a different metal level plan with the same issuer.

Response: These comments are outside the scope of the proposal; however, we clarify that HHS does allow issuers the option to preserve or to re-set progress towards accumulators for enrollees who switch plans mid-year.

Comment: Some commenters expressed support for this proposal based on a misunderstanding that it would allow Exchange enrollees who become newly *eligible* for CSRs to change to a silver-level QHP if they elect to change their QHP.

Response: We clarify that this flexibility already exists through § 155.420(a)(4)(ii), newly designated by this final rule as § 155.420(a)(4)(ii)(A).

Comment: Several commenters expressed strong support for providing State Exchanges with flexibility related to special enrollment period policy implementation, explaining that any special enrollment period changes require significant State Exchange effort and potentially unpredictable costs. Additionally, several commenters expressed the belief that this provision does provide Exchanges with flexibility in terms of whether and when to implement it.

Response: While we generally support flexibility for State Exchanges' policy and operations, we will continue to require all Exchanges to implement plan category limitations as established at § 155.420(a)(4), including changes finalized in this rule. These limitations are necessary to prevent adverse selection and to protect the individual market risk pool. To provide Exchanges with additional time to comply with new plan category limitations finalized in this rule, we are delaying the effective date of these changes to January 2022.

b. Special Enrollment Period Limitations for Enrollees Who Are Dependents

We proposed to apply the same plan category limitations to dependents who are currently enrolled in Exchange coverage that applies to current, non-dependent Exchange enrollees. We are finalizing this policy as proposed.

As discussed in the preceding section of this preamble, under § 155.420(a)(4)(i) and (a)(4)(iii)(B), enrollees who newly add a dependent through most types of special enrollment periods may add the dependent to their current QHP or enroll the dependent in a separate QHP.⁹⁶ Specifically, § 155.420(a)(4)(i) establishes that if an enrollee has gained a dependent in accordance with § 155.420(d)(2)(i), the Exchange must allow the enrollee to add the dependent to his or her current QHP. But if the current QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b), or, at the option of the enrollee or dependent, enroll the dependent in any separate QHP.⁹⁷ Per § 155.420(a)(4)(iii)(B), if a dependent qualifies for a special enrollment period not related to becoming a new dependent, and an enrollee is adding the dependent to his or her QHP, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the QHP's business rules do not allow the dependent to enroll in that plan, 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), or enroll the new qualified individual in a separate QHP. Finally, § 155.420(a)(4)(iii)(A) requires 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).

Per § 155.420(a)(2), a dependent refers to any individual who is or who may become eligible for coverage under the terms of a QHP because of a relationship to a qualified individual or enrollee. As described in the proposed rule, the rules

at § 155.420(a)(4) did not previously address all situations in which a current enrollee is a dependent of a qualified individual who is newly enrolling in Exchange coverage through a special enrollment period. For example, the current rules do not explicitly address what limitations apply when a mother loses her self-only employer-sponsored coverage, thereby gaining eligibility for a special enrollment period for loss of MEC, and seeks to be added as an enrollee to the Exchange coverage in which her two young children are currently enrolled. Applying the limitations at § 155.420(a)(4) to such circumstances is consistent with HHS's goals of establishing equivalent treatment for all special enrollment period eligible qualified individuals, and preventing enrollees from changing plans in the middle of the coverage year based on ongoing or newly emerging health issues. Preamble language from the 2017 Market Stabilization Proposed Rule explained that the requirement at § 155.420(a)(4)(iii) would extend to enrollees who are on an application where a new applicant is enrolling in coverage through a special enrollment period, using general terms to convey that restrictions should apply to enrollees and newly-enrolling individuals regardless of whether the new enrollee is a dependent.⁹⁸

To ensure that Exchange enrollees and qualified individuals are treated consistently under our special enrollment period rules, we proposed to apply the same limitations to dependents who are currently enrolled in Exchange coverage that applies to current, non-dependent Exchange enrollees. Specifically, we proposed to add a new § 155.420(a)(4)(iii)(C) to establish that the Exchange must allow a qualified individual who is not an enrollee, who qualifies for a special enrollment period and has one or more dependents who are enrollees, to add him or herself to a dependent's current QHP; or, per similar existing rules at § 155.420(a)(4)(iii)(B), if the QHP's business rules do not allow the qualified individual to enroll in such coverage, to enroll with his or her dependent(s) in 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), or enroll him or herself in a separate QHP.

As proposed, § 155.420(a)(4)(iii)(C) would be parallel to § 155.420(a)(4)(iii)(B), which applies plan category limitations to current enrollees whose dependent(s) qualify for a special enrollment period to newly

enroll in coverage, and specifies that the Exchange must permit the enrollee to change plans in order to add the dependent when the enrollee's current plan's business rules do not permit adding the dependent, notwithstanding whether the enrollee also qualifies for a special enrollment period. In other words, as proposed,

§ 155.420(a)(4)(iii)(C) would apply plan category limitations in allowing currently enrolled dependents who are enrolled in a plan that has business rules that do not permit the non-dependent to be added to the enrollment, to change plans in order to enroll together with the non-dependent.

Current regulations at § 147.104(b)(2)(iii) provide that § 155.420(a)(4) does not apply off-Exchange. Therefore, the existing and proposed requirements and restrictions under § 155.420(a)(4) do not apply off-Exchange. However, our regulations do not prohibit issuers off-Exchange from newly enrolling with currently enrolled dependents a non-dependent household member(s) who qualifies for a special enrollment period, or from newly enrolling dependent household members who qualify for a special enrollment period with currently enrolled individuals of whom they are a dependent, to the extent consistent with applicable state law.

Comment: Several commenters supported this proposal based on their position that it is appropriate to apply the same limitations to any individual seeking to newly enroll in Exchange coverage with a currently-enrolled household member(s), and a few supported this proposal because it would simplify special enrollment period rules. One of these commenters asked that HHS continue not to apply the plan category limitations policy to off-Exchange enrollments.

Response: We agree with these comments, and note that at this time we do not plan to apply plan category limitations off-Exchange.

Comment: Multiple commenters supported this proposal, but misunderstood it to be either the creation of a new special enrollment period or of a new process for those who qualify for an existing special enrollment period to allow parents or guardians to add themselves to a dependent's Exchange coverage.

Response: Here, we clarify that the proposal would not create a new special enrollment period or incorporate additional flexibility into existing plan category limitations rules; in fact, it clarifies that these limitations apply to Exchange enrollees who are dependents in the same way that they apply to

⁹⁶ Section 155.420(a)(4)(i) and (a)(4)(iii)(B) also provide that alternatively, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in 45 CFR 156.140(b).

⁹⁷ Per § 155.420(a)(2), "dependent" has the same meaning as it does in 26 CFR 54.9801-2, referring to any individual who is or who may become eligible for coverage under the terms of a QHP because of a relationship to a qualified individual or enrollee.

⁹⁸ 82 FR at 10986.

Exchange enrollees who are not dependents.

Comment: Additionally, one commenter misunderstood the proposal to be a change in how the Federally-facilitated Exchanges operationalize special enrollment periods for individuals newly enrolling in coverage with dependents.

Response: We clarify that we are not proposing any changes to how Exchanges using the Federal platform operationalize special enrollment periods for these individuals, including how these Exchanges send this type of enrollment to issuers.

Comment: Several commenters opposed this proposal, citing opposition to plan category limitations more generally. As discussed above, one commenter asked that HHS provide State Exchanges with flexibility in terms of when, and whether, to implement plan category limitations.

Response: While we generally support flexibility for State Exchanges' policy and operations, we will continue to require all Exchanges to implement plan category limitations as established at § 155.420(a)(4), including changes finalized in this rule. These limitations are necessary to prevent adverse selection and to protect the individual market risk pool.

Comment: Some commenters stated that a household should be able to reassess plan choice, including choice of metal level, in situations where a parent or guardian newly enrolls in Exchange coverage with his or her dependents. These commenters expressed doubt that permitting this flexibility would cause adverse selection.

Response: As discussed in the proposed rule, we agree with comments that expressed support for applying plan category limitations to all Exchange enrollees in the same way. Relatedly, we do not think that Exchange enrollees who are dependents are any less likely than enrollees who are not dependents to change to a different metal level plan through a special enrollment period due to ongoing health needs during the coverage year. Therefore we believe it is appropriate to apply the same plan category limitations to all enrollees, whether or not they are dependents.

Comment: One commenter requested clarification of the proposed regulation text; specifically, how it would impact Exchange enrollees who are dependents and whose parent or guardian is newly enrolling in coverage with them, and who themselves are also eligible for a special enrollment period.

Response: Exchange enrollees who are dependents and whose parent or guardian is newly enrolling in coverage

with them through a special enrollment period, and who themselves are also eligible for a special enrollment period, will be limited based on the rules at § 155.420(a)(4) that apply to them. For example, if a parent enrolls in coverage with her dependent child through a special enrollment period due to a move for which they both qualify, then per § 155.420(a)(4)(iii)(A), the currently-enrolled dependent may change to a QHP of the same metal level as his current plan (or one metal level higher or lower, if no such QHP is available). Per § 155.420(a)(iii)(C), the parent may enroll in her child's QHP, or, if the QHP's business rules do not allow her to enroll, the Exchange must allow her and her child to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), or enroll herself in a separate QHP of any metal level.

c. Special Enrollment Period Prospective Coverage Effective Dates

We proposed that in the Exchanges using the Federal platform, special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection. Specifically, we proposed to amend § 155.420(b)(3) for improved clarity and to specify how Exchanges using the Federal platform would implement the proposal. We are finalizing these policies as proposed, but delaying the effective date until January 2022 to allow the sufficient time to implement these changes.

Under regular special enrollment period effective date rules at current § 155.420(b)(1), the Exchange is required to ensure a coverage effective date of the first day of the following month for individuals who select a QHP between the 1st and the 15th day of any month. The Exchange was required to ensure a coverage effective date of the first day of the second following month for individuals who select a QHP between the 16th and the last day of any month. Under those rules, it could take as many as 47 days from plan selection to effectuate coverage under a special enrollment period (that is, from the 16th of a month to the first of the next following month; or for example, from July 16 to September 1). In the Exchanges using the Federal platform and pursuant to § 155.420(b)(1), those rules apply to special enrollment periods provided under § 155.420(d)(3), (d)(6)(i), (ii), (iv), and (v), and (d)(7), (8), (10), and (12). Under other special enrollment periods, such as those under § 155.420(d)(4), (5), and (9), in the Exchanges using the Federal platform,

the consumer is generally offered a choice of regular effective dates that would apply under § 155.420(b)(1), or an effective date that is retroactive to the date that would have applied if not for the triggering event. In addition, under § 147.104(b)(5), the coverage effective date rules in § 155.420(b) apply to each of those special enrollment periods to the extent they apply off-Exchange, as specified in § 147.104(b)(2)(i).

These regular special enrollment period effective date rules under § 155.420(b)(1), along with the initial open enrollment period effective date rules under § 155.410(c), were originally designed to provide issuers several weeks to collect binder payments, mail identification cards, and complete other administrative actions prior to the policy's start date. However, QHP issuers that offer coverage through the Federal Exchange, already effectuate coverage and process changes in circumstance using first-of-the-month rules. In 2017, issuers processed 88 percent of special enrollment periods for individuals newly enrolling in coverage through Exchanges using the Federal platform under accelerated or retroactive effective date rules.⁹⁹ HHS internal data on enrollments through Exchanges using the Federal platform in 2018 indicates that issuers processed a majority of changes in circumstances (including those resulting in special enrollment periods) under accelerated or faster effective date rules. Because issuers in Exchanges using the Federal platform routinely effectuate coverage on a shorter timeframe, we do not anticipate that this change would be difficult for issuers to implement.

Additionally, we explained that as a program integrity measure, we believe any enrollment changes related to changes in eligibility for Exchange coverage or for insurance affordability programs should be implemented as soon as practicable. This is particularly important for consumers with special enrollment periods based on changes in eligibility for APTC under § 155.420(d)(6)(i) and (ii), which currently follow regular effective date rules in the Exchanges using the Federal platform.

As discussed in the proposed rule, the provision will permit Exchanges, including Exchanges using the Federal platform, and issuers to more rapidly implement changes in QHP enrollment, particularly those related to changes in financial assistance eligibility, and

⁹⁹ Centers for Medicare & Medicaid Services, The Exchanges Trends Report (July 2, 2018), available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-3.pdf>.

would standardize prospective special enrollment period effective dates across the Exchanges using the Federal platform, such that consumers eligible for prospective coverage would have a single effective date. It will also help reduce consumer confusion regarding different effective date rules and minimize gaps in coverage.

Finalizing this proposal will also allow State Exchanges the flexibility to retain current special enrollment period regular effective date rules or to adopt the approach that will be taken in the Exchanges using the Federal platform. State Exchanges already had flexibility under § 155.420(b)(3) to effectuate coverage in a shorter timeframe if their issuers agree. Several State Exchanges had already transitioned to faster than regular effective date rules for special enrollment periods. Under these changes, State Exchanges may retain their current effective date rules or implement faster ones without needing to demonstrate issuer concurrence.

By reference, the effective-date-of-coverage rules at § 155.420(b) apply off-Exchange, under § 147.104(b)(5). The proposal would continue to provide the applicable state authority with flexibility regarding the options for effective dates under current rules for off-Exchange coverage.

This change will also help reduce confusion around binder payment deadlines, since these deadlines depend on a policy's coverage effective date. Accordingly, we proposed to make updates to binder payment deadlines in § 155.400(e)(1)(ii) to ensure that special enrollment periods using effective dates under revised § 155.420(b)(3) would also be subject to the same binder payment rules as other special enrollment periods that are effective the first of the month following plan selection. Because the Exchanges using the Federal platform would no longer be following regular coverage effective dates for special enrollment periods under § 155.420(b)(1), we also proposed to remove reference to that provision in § 155.400(e)(1)(i) and to replace "regular effective dates" in § 155.400(e)(1)(iii) with a reference to § 155.420(b)(3). This latter change provides that in the Exchanges using the Federal platform, coverage would be effective on the first of the month following plan selection for consumers who are eligible for retroactive coverage but just pay 1 month's premium and receive only prospective coverage. This change will help ensure that prospective effective dates across the Exchanges using the Federal platform are streamlined under one rule.

We solicited comments on these proposals.

Comment: Most commenters supported this proposal, noting that it will reduce consumer confusion and minimize gaps in coverage. Several commenters stressed the importance of continued flexibility for State Exchanges. One commenter cautioned that this provision could create operational challenges that are difficult to overcome if it is implemented without accounting for a reasonable timeframe for binder payment to effectuate coverage. A commenter urged HHS to ensure that controls are in place to reduce gaming. Specifically, the commenter asked that HHS review current special enrollment period verification processes and make any updates needed to verify eligibility for first of the month coverage following special enrollment periods.

Response: We agree with commenters that this provision will help reduce coverage gaps for consumers who enroll with a special enrollment period and, by harmonizing with coverage effective dates that apply to many of the most common special enrollment periods, will also reduce consumer confusion regarding enrollment through special enrollment periods. As we noted in the preamble to the proposed rule, because issuers in Exchanges using the Federal platform routinely effectuate coverage on a shorter timeframe, we do not anticipate that this change will be difficult for issuers to implement. We continue to monitor the special enrollment period verification process. If any changes are needed to verify eligibility for special enrollment periods that are effective on the first of the month following plan selection, we will explore solutions. Further, current special enrollment period verification processes require many enrollments submitted through the Federal platform to be pended until after verification, after which the enrollment will be released to the issuer with the appropriate effective date. Therefore, we do not anticipate this change will result in additional consumer gaming.

Comment: One commenter requested that this provision be implemented off-Exchange as well, while one commenter asked HHS to confirm that proposed changes for on-Exchange enrollments alone do not seek to regulate existing off-Exchange practices.

Response: Because we believe states are generally in the best position to determine the effective dates that apply in State Exchanges and off-Exchange, we are limiting this provision to QHPs on the Exchanges using the Federal platform. States will continue to have

the same flexibility off-Exchange and in State Exchanges to adopt earlier effective dates as they currently have.

We are finalizing the rule as proposed, but delaying the effective date until January 2022 to allow sufficient time to implement these changes.

d. Special Enrollment Period Retroactive Coverage Effective Dates

We proposed to eliminate the option for a consumer whose enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, under certain circumstances, to elect a coverage effective date that is no more than 1 month later than the effective date the consumer would otherwise have had but for the delay. This provision will align the retroactive effective date and binder payment rules so that any consumer who is eligible to receive retroactive coverage, whether due to a special enrollment period, a favorable eligibility appeal decision, or a special enrollment period verification processing delay, has the option to pay the premium due for all months of retroactive coverage through the first prospective month of coverage, or only the premium for 1 month of coverage and receive prospective coverage only. Specifically, we proposed to eliminate § 155.420(b)(5).

We are finalizing this policy as proposed.

Section 155.400(e)(1)(iii) states that for coverage to be effectuated under retroactive special enrollment period effective dates, as provided for in § 155.420(b)(2), a consumer's binder payment must include the premium due for all months of retroactive coverage through the first prospective month of coverage. If only the premium for 1 month of coverage is paid, only prospective coverage should be effectuated, in accordance with regular effective dates. As an example, a consumer has a special enrollment period that is not subject to verification with a March 1 effective date, but the enrollment is delayed due to an Exchange error. The issuer does not receive the transaction until April 15. Under this rule, to effectuate retroactive coverage beginning March 1, the issuer must receive premiums for March, April, and May. If the issuer only receives a premium payment for 1 or 2 months of coverage, it must effectuate only prospective coverage beginning May 1. This rule was designed to allow consumers who might have difficulty paying for retroactive coverage through a special enrollment period or a favorable eligibility appeal decision to

enroll with prospective coverage only.¹⁰⁰

The Market Stabilization Rule added a different set of binder payment rules at § 155.400(e)(1)(iv) for retroactive effective dates after an enrollment has been delayed due to a prolonged special enrollment period verification under § 155.420(b)(5).¹⁰¹ Under current rules, if a consumer's enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, and the assigned effective date would require the consumer to pay 2 or more months of retroactive premium to effectuate coverage or avoid cancellation, the consumer has the option to choose a coverage effective date that is no more than 1 month later than had previously been assigned. If the consumer does not move her effective date, her binder payment would be the premium due for all months of retroactive coverage through the first prospective month of coverage, consistent with other binder payment rules. For instance, if the consumer's special enrollment period in the above example were subject to verification, and, as above, the March 1 effective date were pending until April 15 due to pre-enrollment verification, the consumer's only effective date options require payment for retroactive months, unlike the previous example. To effectuate coverage under the special enrollment period verification rules in current §§ 155.400(e)(1)(iv) and 155.420(b)(5), she could either pay the premiums for March, April, and May; or move her effective date forward only 1 month to April 1, and must still pay for April and May coverage.

HHS established the special enrollment period verification effective date rules in response to issuer concerns that delays in special enrollment period verification and an un-checked ability of consumers to move their effective date later (as contemplated in the original version of that paragraph in the 2018 Payment Notice) would result in adverse selection, with healthier enrollees requesting a later effective date and sicker enrollees keeping the original retroactive date. However, we have been able to manage our operational processes so that delays in special enrollment period verification

processing have not materialized. As described in the proposed rule, in 2017, we averaged a response time of 1 to 3 days to review consumer-submitted special enrollment period verification documents and provide consumers a response.¹⁰² The response time in 2018 was substantially similar. Additionally, in 2018 and 2019, we resolved over 800,000 special enrollment period verifications, and fewer than 300 enrollees subject to special enrollment period verification have requested to move forward their effective date under §§ 155.400(e)(1)(iv) and 155.420(b)(5). This indicates that these rules are largely unnecessary.

We also proposed to remove the corresponding cross-reference at § 155.420(b)(1) and the special enrollment period verification binder payment rule at § 155.400(e)(1)(iv). Finally, we proposed to amend § 155.400(e)(1)(iii) to state more explicitly that any consumer who can effectuate coverage with a retroactive effective date, including those whose enrollment is delayed until after special enrollment period verification, also has the option to effectuate coverage with the applicable prospective coverage date by choosing to only pay for 1 month of coverage by the applicable deadline, notwithstanding the retroactive effective date that the Exchange otherwise would be required to ensure.

Standardizing a single binder payment rule for retroactive effective dates will improve operational efficiency for issuers and Exchanges using the Federal platform. Issuers have indicated that it is difficult to determine the appropriate binder payment rule to apply to an enrollment with a retroactive effective date when they receive fewer than all retroactive months of premium, because issuers need to discern whether the consumer's eligibility stems from an appeal, a non-verified special enrollment period, or a special enrollment period with a delay in verification processing. For example, if on March 5, an issuer receives a plan selection for a mother and child enrolling through an adoption special enrollment period with a January 10 effective date, and neither the mother nor child are current enrollees with the issuer, the issuer has no way of knowing whether this transaction was subject to verification. If the issuer in this case only receives 1 month's premium, it would not know whether to cancel the enrollment or effectuate prospective-

only coverage. This change will simplify issuer operations by eliminating that complexity.

Implementing a single set of binder payment rules will help ensure all enrollees (including those subject to special enrollment period verification) can access affordable coverage without being required to pay for months of retroactive coverage that may be prohibitively expensive, and during which most providers would have insisted on direct payment in order to provide health care services.

Finally, by reference, the effective-date-of-coverage rules at § 155.420(b) apply off-Exchange, in accordance with § 147.104(b)(5). Therefore, removing § 155.420(b)(5) will also remove this requirement off-Exchange.

We solicited comments on these proposals, including alternative approaches to streamlining retroactive effective date rules.

Comment: Many commenters supported our proposal. One commenter suggested that to the extent HHS proceeds with the proposal, HHS should afford flexibility to State Exchanges in how they address retroactive coverage.

Response: For the reasons explained elsewhere in this subsection of the preamble, this provision, simply reverts retroactive coverage effective date policy to the policy that was in place prior to the 2018 Payment Notice. State Exchanges were previously required to follow retroactive special enrollment period effective date rules, and this change does not alter that.

Comment: Several commenters asked that we continue to monitor special enrollment period verification speed and return to the earlier process should any delays in verification resume. One commenter urged us to establish a system whereby the consumer is intentionally selecting their effective date on the Exchange and then that date is communicated from Exchanges using the Federal platform. A number of commenters asked for consumers to be able to select partial or full coverage post-appeal, and a group of commenters urged that consumers may have valid reasons for requesting partial retroactive coverage.

Response: HHS will continue to monitor the speed of special enrollment period verification and will reconsider this change if there is evidence of regular and significant delays. We will consider establishing a system whereby a consumer can select their effective date in the application for Exchanges using the Federal platform, but note that such a program would be operationally complex to implement, as would allowing consumers to select partial

¹⁰⁰ If the enrollee pays some, but not all, months of retroactive premium due (two months in the example above), then the issuer would effectuate coverage prospectively. See 2017 Payment Notice, 81 FR at 12272. The issuer could then apply any amount paid in excess of 1 month's premium but less than the full amount needed to effectuate retroactive coverage to the next month's premium, or refund the excess amount to the enrollee, at the enrollee's request.

¹⁰¹ Market Stabilization Rule, 82 FR at 18346.

¹⁰² Centers for Medicare & Medicaid Services, The Exchanges Trends Report (July 2, 2018), available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-3.pdf>.

retroactive coverage post-appeal. Such a system might also present adverse selection concerns.

Comment: Several commenters expressed concern that this proposal would result in challenges for issuers in determining how to proceed with a binder payment in order to effectuate retroactive or prospective coverage. One commenter suggested that HHS should specify that this option should not be allowed for periods during which an individual used covered services.

Response: Under § 155.400(e)(1)(iv), issuers determine a consumer's effective date if the consumer was eligible for retroactive coverage, based on the premium paid. That provision states that for coverage to be effectuated under retroactive special enrollment period effective dates, as provided for in § 155.420(b)(2), a consumer's binder payment must include the premium due for all months of retroactive coverage through the first prospective month of coverage. If only the premium for 1 month of coverage is paid, only prospective coverage should be effectuated, in accordance with regular effective dates. This proposal would simply streamline all retroactive effective date rules, including for consumers who enrollment is pending due to special enrollment verification. These rules apply whether or not an individual was using covered services.

After reviewing the public comments, we are finalizing this provision as proposed.

e. Enrollees Covered by a Non-Calendar Year Plan Year QSEHRA

We proposed to codify the policy that qualifying individuals and dependents who are provided a qualified small employer HRA (QSEHRA) with a non-calendar year plan year would be eligible for the special enrollment period at § 155.420(d)(1)(ii) for qualified individuals and dependents who are enrolled in any non-calendar year group health plan or individual health insurance coverage, to allow the same flexibility for employees and dependents who are provided QSEHRAs as is available to those who are offered individual coverage HRAs.¹⁰³

The HRA rule allows employers to offer HRAs and other account-based group health plans integrated with individual health insurance coverage or Medicare Part A and B or Part C, if

¹⁰³ This preamble refers to a QSEHRA being "provided" as opposed to being "offered" because, per § 146.123(c)(4), an individual coverage HRA eligible employee has an annual opportunity to opt out of and forfeit future payments from the HRA. However, this is not the case for employees and dependents with a QSEHRA.

certain conditions are satisfied.¹⁰⁴ These are called individual coverage HRAs. Among other conditions, an individual coverage HRA must require that the participant and any covered dependent(s) be enrolled in individual health insurance coverage (either on or off-Exchange) or Medicare Part A and B or Part C, for each month that they are covered by the individual coverage HRA.¹⁰⁵

The HRA rule provides a special enrollment period to employees and dependents who newly gain access to an individual coverage HRA to enroll in individual health insurance coverage, or to change to other individual health insurance coverage in order to maximize the use of their individual coverage HRA.¹⁰⁶ In addition, because employees and dependents with a QSEHRA¹⁰⁷ generally must be enrolled in MEC,¹⁰⁸ and one category of MEC is individual health insurance coverage, the HRA rule provides that individuals who are newly provided a QSEHRA also qualify for the new special enrollment period.

The HRA rule also solicited and addressed public comments on whether the new special enrollment period should be available on an annual basis at the beginning of each new plan year of the employee's individual coverage HRA or QSEHRA, particularly if the new plan year is not aligned with the calendar year.¹⁰⁹ In the preamble to the HRA rule, HHS stated that it had determined that individual coverage HRA or QSEHRA enrollees should have the option to re-evaluate their individual health insurance coverage for each new HRA plan year, regardless of whether the HRA is provided on a calendar year basis. Therefore, while the HRA rule did not make the new individual coverage HRA and QSEHRA special enrollment period available on an annual basis, it clarified that those who are enrolled in an individual coverage HRA with a non-calendar year plan year—that is, the HRA's plan year

¹⁰⁴ 84 FR 28888 (June 20, 2019).

¹⁰⁵ For purposes of individual coverage HRAs, references to individual health insurance coverage do not include individual health insurance coverage that consists solely of excepted benefits. See 45 CFR 146.123(c)(1)(i).

¹⁰⁶ See § 155.420(d)(14).

¹⁰⁷ Section 18001 of the Cures Act amends the Code, ERISA, and the PHS Act to permit an eligible employer to provide a QSEHRA to its eligible employees. See IRS Notice 2017-67, 2017-11 IRB 1010, for related guidance: <https://www.irs.gov/pub/irs-drop/n-17-67.pdf>.

¹⁰⁸ Generally, payments from a QSEHRA to reimburse an eligible employee's medical care expenses are not includible in the employee's gross income if the employee has coverage that provides MEC as defined in Code section 5000A(f), which includes individual health insurance coverage.

¹⁰⁹ 84 FR at 28955 through 28956.

begins on a day other than January 1—will be eligible annually for the special enrollment period under existing regulations at § 155.420(d)(1)(ii), because individual coverage HRAs are group health plans. While the HRA rule did not make any changes to § 155.420(d)(1)(ii), the preamble of the rule expressed HHS's intention to treat a QSEHRA with a non-calendar year plan year as a group health plan for the limited purpose of qualifying for this special enrollment period, and to codify this interpretation in future rulemaking.¹¹⁰

As HHS explained in the HRA rule, we believe making the non-calendar year plan year special enrollment period available annually to individual market enrollees with a non-calendar year plan year individual coverage HRA or QSEHRA appropriately provides employers with flexibility to offer individual coverage HRAs or provide QSEHRAs on a 12-month cycle that meets their needs. The expansion also allows employees and their dependents the flexibility to re-assess their individual health insurance coverage options at the same time that the terms of their individual coverage HRA or QSEHRA may change. We believe accessing this non-calendar year plan year special enrollment period may be important to some individuals, including those who wish to change their individual health insurance plan due to a change in the terms of their individual coverage HRA or QSEHRA. However, we anticipate that most individuals with an individual coverage HRA or a QSEHRA would not seek to change their individual coverage outside of the individual market open enrollment period when their new HRA plan year starts since doing so would generally cause their accumulators to reset. Therefore, we do not anticipate significant additional administrative burden for issuers or a significant increase in the potential for adverse selection in the individual market associated with this special enrollment period. In addition, HHS believes that the applicability of plan category limitations to the non-calendar year plan year special enrollment period for Exchange enrollees will further mitigate the potential risk of adverse selection.

As discussed in the HRA rule preamble,¹¹¹ under section 2791 of the PHS Act, section 733 of ERISA, and section 9831 of the Code, QSEHRAs are not group health plans,¹¹² and

¹¹⁰ Id. at 28956.

¹¹¹ 84 FR at 28956.

¹¹² One exception to this general rule is that a QSEHRA continues to be treated as a group health

employees and their dependents with a QSEHRA do not qualify for the non-calendar year special enrollment period as our special enrollment period rules are currently written. Therefore, we proposed to amend § 155.420(d)(1)(ii) to codify that individuals and dependents who are provided a QSEHRA with a non-calendar year plan year may qualify for this special enrollment period. We noted that this special enrollment period also is incorporated by reference in the guaranteed availability regulations at § 147.104(b)(2). Therefore, individuals provided a non-calendar year plan year QSEHRA would be entitled to a special enrollment period to enroll in or change their individual health insurance coverage through or outside of an Exchange.

We solicited comment on this proposal.

After consideration of the comments received, we are finalizing this policy and the accompanying update to § 155.420(d)(1)(ii) as proposed.

Comments: Many commenters supported this proposal. Several expressed support because it aligns special enrollment period eligibility for consumers whose employer provides them with a QSEHRA with that of consumers whose employer offers them an individual coverage HRA, and several supported it due to their general support of all provisions to promote the use of HRAs. Some commenters supported the proposal, but misunderstood it to be the creation of a new special enrollment period for consumers who are newly provided with a QSEHRA.

Response: We clarify that employees and dependents newly provided with a QSEHRA are already included in the special enrollment period at § 155.420(d)(14), which we established in the HRA Rule for individuals, enrollees, and dependents who newly gain access to an individual coverage HRA or to a QSEHRA. We appreciate the general support for allowing employees and dependents with a non-calendar year plan year QSEHRA to change plans annually based on their QSEHRA plan year start date, and we are finalizing the policy and the accompanying update to § 155.420(d)(1)(ii) as proposed.

6. Termination of Exchange Enrollment or Coverage (§ 155.430)

a. Enrollee-Initiated Terminations Upon a Finding of Dual Enrollment in Medicare via PDM

Consistent with our discussion of voluntary terminations upon a finding of dual enrollment in the preamble to § 155.330, we proposed to revise paragraph (b)(1)(ii) by removing the requirement that the Exchange must initiate termination of a Medicare dual enrollee's QHP coverage upon completion of the redetermination process specified in § 155.330. We also proposed to add to § 155.330(b)(1)(ii) a reference to the process and authority outlined in § 155.330(e)(2) to align with the proposed changes to § 155.330(e)(2)(i)(D), discussed in the preamble on the proposed rule at § 155.330. For more detailed discussions of these proposals, please see the preamble discussion in the proposed rule at § 155.330. We are finalizing these revisions as proposed.

Comment: We received multiple comments in support of Medicare PDM as an effort to improve Exchange program integrity. These commenters agreed that the process has a positive impact on consumers as it helps inform Exchange enrollees of their enrollment in potentially duplicative other MEC such as certain Medicare. Commenters also noted that the proposed changes help support efficient Exchange operations with respect to the Medicare PDM process while minimizing burden on stakeholders such as states, issuers, consumers, and taxpayers. Commenters appreciated that the proposed changes continue to support flexibility for State Exchanges by providing all Exchanges with the option to allow applicants to provide written consent for Exchanges to end their QHP coverage if later found to be enrolled in Medicare.

Response: We agree with commenters that the Medicare PDM process is an important tool for Exchange program integrity. We also agree that the process helps inform consumers of their enrollment in potentially duplicative other MEC such as certain Medicare and helps consumers avoid a tax liability for having to repay APTC received during months of overlapping coverage when reconciling at the time of annual federal income tax filing.

After reviewing the public comments, we are finalizing as proposed.

b. Effective Dates for Retroactive Termination of Coverage or Enrollment Due to Exchange Error

In the proposed rule, we proposed to update the rule that defines the effective

date for enrollees seeking retroactive terminations due to a technical error to allow their coverage to end retroactive to the date they attempted the termination, without the 14-day advance notice requirement that was otherwise eliminated in the 2019 Payment Notice. We are finalizing this policy as proposed.

The 2019 Payment Notice amended § 155.430(d)(2) to allow additional flexibility regarding the effective date for enrollee-initiated terminations. This flexibility included permitting Exchanges—at the option of the Exchange—to provide for enrollee-initiated terminations to be effective on the date on which the termination was requested by the enrollee, or on another prospective date selected by the enrollee. Previously, enrollees generally had to provide 14-days advance notice before termination became effective. Corresponding updates to reflect the new flexibilities were not made to § 155.430(d)(9), which defines the effective date for retroactive terminations due to a technical error as described in paragraph (b)(1)(iv)(A). The current provision specifies that termination in these circumstances will be no sooner than 14 days after the date that the enrollee can demonstrate he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, unless the issuer agrees to an earlier effective date as set forth in § 155.430(d)(2)(iii).

To ensure that enrollees who suffered technical errors are put in the position they would have been absent the technical error, we proposed to align § 155.430(d)(9) with the provisions for enrollee-initiated terminations at § 155.430(d)(2).

We solicited comment on this proposal.

Comment: While fewer than 10 commenters commented on this proposal, all were in support. A few commenters requested retroactive terminations not be granted if the enrollee continued to incur claims.

Response: This proposal simply addresses the oversight of not uniformly removing the 14-day waiting period for terminations in previous regulation. It does not revisit eligibility for retroactivity under the rule. We expect the number of claims that will be reversed for enrollees whose termination was delayed due to technical error will be very low, given that most consumers taking independent steps to end their coverage would have little reason to keep using it.

After reviewing the public comments, we are finalizing as proposed.

7. Eligibility Pending Appeal (§ 155.525)

As discussed in the proposed rule, we are considering whether changes to § 155.525 governing eligibility pending appeals are necessary or prudent to provide greater clarity to Exchanges, issuers, and consumers who appeal Exchange determinations, and asked for public comment in the event that we decide to propose regulatory changes in the future. As such, we are not finalizing any changes to eligibility pending appeal in this rule.

Under § 155.525, when an appellant accepts eligibility pending appeal, an Exchange must continue the appellant's eligibility for enrollment in a QHP, APTC, and CSR, as applicable, in accordance with the level of eligibility that was in effect immediately before the eligibility redetermination that the consumer is appealing. We solicited comment on various aspects of the administration of this provision, including: (1) The retroactive application of benefits relative to an appellant's enrollment and applicability of plan category limitations; (2) the advisability of establishing a timeliness standard, whether Exchanges should have the flexibility to determine their own timeliness standards, and what a reasonable timeliness standard should be; (3) how life events and other reported eligibility changes interact with eligibility pending appeal; (4) how the retroactive implementation of an appeal decision interacts with eligibility pending appeal; and (5) how eligibility pending appeal interacts with the consequences of non-payment of premiums. While we decided against proposing any changes to the regulations at this time, we invited comments on this topic. We received the following comments, and our response follows.

Comment: Several commenters were supportive of preserving state flexibility in how State Exchanges administer this provision. A few commenters noted the current absence of data about appeals generally and recommended the provision of data to inform future rulemaking in this area. For example, it was observed that issuers do not have adequate access to data on enrollees who are appealing an eligibility determination, which makes it difficult to offer comment on these proposals and recommend guardrails. We also received a comment questioning the need for any regulatory changes, stating that the current system of administering this provision has been functioning largely as intended. Another commenter advised against any changes to the regulations that reduce or eliminate

consumer flexibility while consumers exercise their constitutionally provided due process rights. Finally, one commenter expressed a belief that the most accurate understanding of eligibility pending appeal is not that the appellant is theoretically eligible for certain benefits, but instead that the appellant is in fact able to access the benefits for which they were eligible immediately before the eligibility determination on appeal. This commenter noted that in its state, the provision of eligibility pending appeal involves additional state-based premium and cost-sharing assistance for qualifying residents below 300 percent of the federal poverty level, which are in addition to the APTC and CSRs provided at the federal level.

With respect to the permissibility of changes to plan enrollment, we received many comments supporting a policy that would allow appellants who are granted eligibility pending appeal to enroll in any Exchange plan without regard to issuer or metal level. One of these commenters also recommended that an appellant who is receiving eligibility pending appeal be permitted to switch plans at the end of the appeal, stating that if the appeal is upheld, the appellant will experience a termination of the APTC and may want to switch to a lower metal level plan. Conversely, another commenter supported the ability of appellants who win their appeals to select a different plan from the same issuer, stating that there is a need to balance flexibility with appropriate controls to ensure that frivolous appeals are not filed for individuals who are looking for any opening to change plans, which in turn could create financial and premium instability for health plans. One commenter was in favor of offering retroactive as well as prospective implementation of eligibility pending appeal, while another commenter expressed opposition to prospective implementation on the grounds that doing so would eliminate the very protection eligibility pending appeal is intended to address. One commenter stated that unrestricted plan and issuer changes would be extremely confusing to consumers, while another commenter recommended robust consumer education materials to help individuals understand the implications of their plan choices while they are receiving eligibility pending appeal. In the context of implementing an appellant's request for eligibility pending appeal retroactively, two commenters advised HHS to consider the impact of retroactive changes to plans, products,

metal levels or issuer on adverse selection. These commenters noted that retroactive enrollment changes are problematic due to claims reprocessing, changing benefits, and state prompt pay laws, and may expose appellants to increased out-of-pocket costs for services they already received. Finally, we received a comment urging HHS to provide autonomy to states in this area, as rules allowing unrestricted plan and issuer changes would require substantial technological rule and code changes that would likely come with a significant financial burden.

We received numerous comments in opposition to any timeliness standard that would apply to an appellant requesting eligibility pending appeal. One of these commenters noted that consumers who had initially filed an appeal on their own may later appoint an authorized representative or legal counsel who might inform them of this right; similarly, consumers who did not elect eligibility pending appeal at the outset of the appeal may later encounter a situation necessitating the coverage and financial help eligibility pending appeal may provide. We also received several comments supporting either a 15-day or 30-day timeframe in which to request eligibility pending appeal from the receipt date of the appeal request or from the date of the acknowledgment notice, with most of these commenters also supporting an extension if there were exceptional circumstances precluding a timely request. One commenter recommended that Exchanges be permitted to establish their own timeliness standard and determine whether to establish a good cause exception, while another recommended that HHS leave the process as it currently exists in place.

We received a number of comments recommending that consumers who experience a life event during the pendency of the appeal have their appeals considered resolved in their favor, with one commenter noting that the life event, once reported, may negate the need for an appeal. Several commenters noted the importance of appellants being able to report life events even while receiving eligibility pending appeal in order for appellants and members of the household to access coverage on a timely basis. One commenter advised that Exchanges be given the flexibility to determine how to proceed with processing these eligibility changes. Relatedly, one commenter, drawing on its experience administering an Exchange, observed that the hearing decision of an independent hearing officer must be implemented as issued, in order to preserve the fairness and

independence of the hearing process. This commenter stated that if a hearing officer ordered the Exchange to provide an appellant with the option for retroactive coverage at a given level of eligibility, the Exchange would do so, in situations where the appellant had been receiving eligibility pending appeal at a level less generous than what the hearing officer's decision awarded; however, the hearing decision would not be implemented retroactively in situations where a less generous eligibility level was awarded than the eligibility level provided by eligibility pending appeal.

In response to our request for comments on the applicability of the grace period to individuals enrolled in Exchange coverage and receiving eligibility pending appeal, we received a number of comments recommending a 3-month grace period as well as a general prohibition on termination of coverage during the pendency of the appeal. One commenter was in favor of the ability of appellants receiving eligibility pending appeal to select the effective date of retroactive coverage, effectuate the first month of retroactive coverage, and be given a reasonable amount of time to bring their payment current. Another commenter expressed a belief that the grace period does apply and supported a rule clarifying its applicability to the extent that it was not sufficiently clear under the existing regulations. Finally, we received a comment recommending that the enrollee be required to pay the current billed amount and another comment stating that appellants should not be treated any differently than non-appellants with respect to coverage termination.

Response: We thank the commenters for the feedback on these issues. We did not propose and are not finalizing any changes to rules governing eligibility pending appeal. This feedback, however, will help inform future policy in this area.

8. Eligibility Standards for Exemptions (§ 155.605)

a. Required Contribution Percentage (§ 155.605(d)(2))

In the proposed rule, we used the proposed 2021 premium adjustment percentage to calculate the excess of the rate of premium growth over the rate of income growth for 2013 to 2020 as $1.3542376277 \div 1.3094029651$, or 1.0342405385 . This resulted in a proposed required contribution percentage for 2021 of 8.00×1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of

one percent. We are finalizing the required contribution percentage as proposed.

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. We proposed to calculate the required contribution percentage for the 2021 benefit year, using income and premium growth data for the 2013 and 2020 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 proposed as the measure for premium growth the 2021 premium adjustment percentage of 1.3542376277 (or an increase of about 35.4 percent over the period from 2013 to 2020). This reflects an increase of about 5.0 percent over the 2020 premium adjustment percentage ($1.3542376277 / 1.2895211380$).

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 using the National Health Expenditure Accounts (NHEA) data, the rate of income growth for 2021 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year (\$58,821 for 2020) exceeds per capita PI for 2013 (\$44,922), carried out to ten significant digits. The ratio of per capita PI for 2020 over the per capita PI for 2013 is estimated to be 1.3094029651 (that is, per capita income growth of about 30.9 percent).¹¹³ This rate of income growth between 2013 and 2020 reflects an increase of approximately 4.6 percent over the rate of income growth for 2013 to 2019 ($1.3094029651 / 1.2524152976$) that was used in the 2020 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.).¹¹⁴

Using the 2021 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2020 is $1.3542376277 \div 1.3094029651$, or 1.0342405385 . This results in the required contribution percentage for 2021 of 8.00×1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.04 percentage points from 2020 (8.27392–8.23702).

We solicited comment on the required contribution percentage. After reviewing public comments, we are finalizing the required contribution percentage for 2021 at 8.00×1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of one percent. The following is a summary of the public comments we received on the required contribution percentage. We address comments regarding the measures used

¹¹³ The 2013 and 2020 per capita personal income figures used for this calculation reflect the latest NHEA data as of the publication of the proposed rule. These data were published on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS website, which can be accessed by clicking the "NHE Projections 2018–2027—Tables" link located in the Downloads section at <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 also available on the CMS website.

¹¹⁴ 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.

to calculate the excess of the rate of premium growth over the rate of income growth in the section of the preamble related to the premium adjustment percentage, later in this rule.

Comment: One commenter asked that we not increase the required contribution percentage from the value finalized for 2020, as increases to this value reflect increases in the percentage of income enrollees may have to contribute toward health care, thereby reducing affordability for these consumers. A few other commenters expressed concern with the increase in this value as part of their comments on the proposed premium adjustment percentage.

Response: HHS is required to update the required contribution percentage annually by section 5000A(e)(1)(D) of the Code. The updated contribution percentage is used, among other things, for purposes of determining whether individuals above the age of 30 qualify for an affordability exemption, so that they can be eligible to enroll in catastrophic coverage under § 155.305(h). As such, after reviewing the public comments, we are finalizing the required contribution percentage for 2021 at 8.00×1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of one percent.

9. Quality Rating Information Display Standards for Exchanges (§§ 155.1400 and 155.1405)

We proposed to amend §§ 155.1400 and 155.1405 to codify the flexibility for State Exchanges that operate their own eligibility and enrollment platforms, to customize the display of quality rating information on their websites to display the quality rating information as calculated by HHS or to display quality rating information based upon certain state-specific customizations of the quality rating information provided by HHS. We are finalizing as proposed.

To implement sections 1311(c)(3) and 1311(c)(4) of the PPACA, we developed the QRS and the QHP Enrollee Experience Survey (collectively referred to as the quality rating information). In the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule¹¹⁵, HHS issued regulations at §§ 155.1400 and 155.1405 to establish quality rating information display standards for Exchanges.¹¹⁶ Consistent

with these regulations, Exchanges must prominently display on their websites, in accordance with § 155.205(b)(1)(iv) and (v), quality rating information assigned for each QHP¹¹⁷, as provided by HHS and in a form and manner specified by HHS.

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 display of quality rating information across the Exchanges. In particular, during plan years 2017, 2018, and 2019, HHS displayed quality rating information on *HealthCare.gov* in a handful of select FFE states as part of a limited pilot program. During this time, State Exchanges that operated their own eligibility and enrollment platforms were given the option to display the quality rating information for their respective QHPs and several of these State Exchanges voluntarily elected to display this information on their State Exchange websites. The QRS pilot involved focused consumer testing of the display of quality rating information to maximize the clarity of the information provided and to assess how the information was displayed and used on Exchange websites.

In August 2019, HHS issued a Quality Rating Information Bulletin to announce the transition away from the QRS pilot to the public display of quality rating information for plan year 2020 by all Exchanges, including FFEs, SBE-FPs, and State Exchanges that operate their own eligibility and enrollment platform.¹¹⁸ This included flexibility for State Exchanges that operate their own eligibility and enrollment platforms to display QHP quality rating information on their websites in the form and manner specified by HHS or with some limited state customizations. Based upon experience during the QRS pilot, we recognize there are benefits to permitting some flexibility for State Exchanges that operate their own eligibility and enrollment platforms to customize the quality rating information for their QHPs. As stated in the proposed rule, we understand that during the QRS pilot, some State Exchanges that operate their own

and Beyond, Final Rule, 79 FR 30240 at 30352 (May 27, 2014).

¹¹⁵ Exchanges can satisfy the requirement to display the QHP Enrollee Survey results by displaying the Quality Rating System (QRS) quality ratings (which incorporate member experience data from the QHP Enrollee Survey). See 79 FR at 30310.

¹¹⁸ Quality Rating Information Bulletin for Plan Year 2020. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf>.

eligibility and enrollment platforms displayed the quality rating information as provided by HHS, while others displayed the quality rating information with certain state-specific customizations in order to best reflect local priorities or information.

Therefore, we proposed to amend §§ 155.1400 and 155.1405 to codify this flexibility and provide State Exchanges that operate their own eligibility and enrollment platforms some flexibility to customize the display of quality rating information for their respective QHPs.

For example, we would allow State Exchanges that operate their own eligibility and enrollment platform to make state-specific customizations, such as to incorporate additional state or local quality information or to modify the display names of the QRS quality ratings. However, we clarified under this approach State Exchanges that operate their own eligibility and enrollment platform could not develop their own programs to replace the quality ratings calculated by HHS. Consistent with the statute, the Secretary remains responsible for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings under these programs across all Exchanges.¹¹⁹ We further noted that we believe the proposed flexibility supports the feedback we received from a Request for Information, entitled "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act and Improving Healthcare Choices to Empower Patients", published in the June 12, 2017 *Federal Register* (82 FR 26885), in identifying ways to reduce burden and promote State Exchange flexibility. We solicited comment on this proposal.

After consideration of the comments received, we are finalizing these changes as proposed.

Comment: All commenters who provided feedback regarding this proposal expressed support for codifying the flexibility for State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information for their respective QHPs. One commenter urged HHS to clarify that states are not permitted to develop their own programs and replace the quality ratings developed by HHS in their entirety.

Response: We are finalizing as proposed and maintain in the final rule that State Exchanges that operate their own eligibility and enrollment platforms have the flexibility to engage

¹¹⁹ See sections 1311(c)(3) and (c)(4) of the PPACA.

¹¹⁵ See the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule; (May 27, 2014), 79 FR 30240 at 30310, available at <https://www.gpo.gov/fdsys/pkg/FR-2014-05-27/pdf/2014-11657.pdf>.

¹¹⁶ Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015

in some customization of the display of quality rating information for their respective QHPs, such as by incorporating additional state or local quality information or by modifying the display names of the QRS quality ratings. However, consistent with sections 1311(c)(3) and 1311(c)(4) of the PPACA, the Secretary of HHS is responsible for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings for QHPs across all Exchanges. Although State Exchanges may continue to provide additional state or local healthcare quality information or display additional state-level quality ratings as part of their plan shopping experience, State Exchanges cannot develop their own programs to replace the quality ratings calculated by HHS because the Secretary remains responsible for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings under these programs across all Exchanges.

Comment: A few commenters requested greater flexibility for State Exchanges that operate their own eligibility and enrollment platforms, including the option for these State Exchanges to perform their own calculations in determining QRS information. One commenter supported the need for common national and performance benchmarks, but noted that State Exchanges should retain the flexibility to modify the QRS rating methodology since periodic and future refinements are expected of the federal quality rating methodology. Further, one commenter suggested that State Exchanges on the Federal platform should be allowed the same flexibility to customize the display of quality rating information.

Response: We support flexibility for State Exchanges that are consistent with the statute and available technical systems. Sections 1311(c)(3) and 1311(c)(4) of the PPACA require each Exchange to provide information to individuals and employers from the rating and enrollee satisfaction systems on the Exchange's website. Therefore, the information from the QRS and the QHP Enrollee Survey must be displayed on each Exchange website. In addition, sections 1311(c)(3) and 1311(c)(4) direct the Secretary of HHS to develop a rating system and a system to assess enrollee satisfaction. Therefore, to be consistent with the statute, the greater flexibility for State Exchanges that operate their own eligibility and enrollment platforms is related to the display of quality rating information and not the development of separate quality ratings. This rule finalizes flexibility for State

Exchanges that operate their own eligibility and enrollment platforms to be able to customize the display of quality rating information. State Exchanges that use the Federal platform, however, would follow the display requirements of the HealthCare.gov system, which is currently unable to accommodate state-specific customizations of this nature.

We clarify that, as outlined in the statute and in the 2015 Market Standards Rule, HHS will continue to calculate federal quality ratings based on data submitted by eligible QHP issuers across Exchanges and using a standardized methodology. HHS will also continue providing federal quality rating information to State Exchanges that operate their own eligibility and enrollment platforms for display on each Exchange website. In this final rule, HHS is allowing certain state-specific modifications to the display of federal quality rating information including incorporating additional state or local quality information or modifying the display names of the quality ratings, for State Exchanges that operate their own eligibility and enrollment platforms. This flexibility does not include the ability to recalculate or modify the quality ratings provided by HHS. As detailed above, sections 1311(c)(3) and 1311(c)(4) of the PPACA assign responsibility for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings for QHPs across all Exchanges to the Secretary. Therefore, we did not propose and are not finalizing changes to permit states greater flexibility to calculate quality ratings for QHPs offered through Exchanges.

We agree that, as with all HHS quality reporting programs and initiatives, periodic evaluation of and refinements to the QRS rating methodology are appropriate and we expect to continue to improve the program with such refinements for future benefit years. HHS will continue to transparently communicate program and methodology refinements and request stakeholder feedback.

Comment: Two commenters requested additional clarification from HHS regarding how and what QRS information would be displayed, including certain state-specific customizations, and on how local and state quality ratings could be incorporated into the greater QRS.

Response: We intend to continue to require display of the QHP quality rating information for all Exchanges and will provide guidance in a subsequent QRS Bulletin, as in previous years, on

the form and manner of display of quality rating information by Exchanges and direct enrollment entities.¹²⁰ The upcoming QRS Bulletin will clarify the quality rating information to be displayed beginning in the individual market open enrollment period for the 2021 plan year, which starts on November 1, 2020.¹²¹

The changes made in this final rule provide flexibility to State Exchanges that operate their own eligibility and enrollment platforms to make certain state-specific customizations to the quality rating information provided by HHS, including the incorporation of additional local and state QHP quality information or the modification of the display names of the quality ratings. State Exchanges that operate their own eligibility and enrollment platforms can determine whether and how to take advantage of this flexibility, including if and how to incorporate local and state quality rating information.

Comment: Two commenters provided general recommendations regarding the display of quality rating information. One commenter encouraged HHS to continue working with issuers and consumers relating to display of QRS information in a meaningful manner and to be transparent in disclosing information on the use of QRS information during plan selection and enrollment. Another commenter requested that if there are changes for a specific display format, sufficient time and funding be provided to State Exchanges that operate their own eligibility and enrollment platforms to implement system changes and that State Exchanges be included early in the development process for any potential changes.

Response: We agree that transparency of information will help issuers, states and consumers make informed decisions related to QHP quality. We will continue working with issuers, consumers, states, quality measurement technical experts, and others to help ensure that the display of quality rating information for QHPs offered on Exchanges is useful, meaningful and understandable to individuals and families shopping for a QHP. We intend to conduct focus groups and cognitive testing directly with consumers

¹²⁰ As part of the Administration's efforts to combat COVID-19, we recently announced the suspension of activities related to the collection of clinical quality measures for the QRS and survey measures for the QHP Enrollee Survey for the 2021 plan year (2020 ratings year). See the COVID-19 Marketplace Quality Initiatives memo, available at: <https://www.cms.gov/files/document/covid-19-and-marketplace-quality-initiatives-memo-final.pdf>.

¹²¹ See 45 CFR 155.410(e)(3).

regarding the enrollee experience survey measures, some of which are part of the QRS. We also anticipate providing consumers with technical assistance if needed and additional materials to clarify the details and uses of QHP quality rating information. We also agree that State Exchanges and other stakeholders should be provided opportunities to give input on potential future changes to the display of quality rating information. We believe it is important to obtain diverse feedback from stakeholders to continue to improve the utility and comprehension of displayed QHP quality rating information and to help inform plan selection. Since this final rule is providing an additional option to State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information for their QHPs, we believe that states that elect to take advantage of this flexibility will have adequate time to make any changes. Should we pursue changes to the formatting or other display requirements in the future, we will keep in mind the comments about providing time for State Exchanges to make the necessary updates to their respective systems to implement any such changes.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Definitions (§ 156.20)

We proposed to remove the definition of the term “generic” at § 156.20 because we proposed a revision at § 156.130(h) which would no longer use the term “generic.” For a discussion of that policy, please see the preamble related to § 156.130(h).

We received no comments on the proposed removal of the term “generic”. Therefore, we are finalizing this change as proposed.

2. FFE and SBE–FP User Fee Rates for the 2021 Benefit Year (§ 156.50)

We proposed maintaining the FFE user fee for all participating FFE issuers at 3.0 percent of total monthly premiums. Likewise, we proposed maintaining a user fee rate of 2.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. These proposed rates were based on internal projections of Federal costs for providing special benefits to FFE and SBE–FP issuers during the 2021 benefit year, as well as estimates of premium increases and enrollment decreases. We stated that we were considering, and we

solicited comment on, lowering the user fee rates below the proposed rates. We are finalizing maintaining the FFE and SBE–FP user fee rates at 3.0 percent and 2.5 percent, respectively, as proposed for the 2021 benefit year.

Section 1311(d)(5)(A) of the PPACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specify that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP. In addition, OMB Circular No. A–25 establishes Federal policy regarding the assessment of user fee charges under other statutes, and applies to the extent permitted by law. Furthermore, OMB Circular No. A–25 specifically provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public. Activities performed by the Federal Government that do not provide issuers participating in an FFE with a special benefit, or that are performed by the Federal government for all QHPs, including those offered through State Exchanges, are not covered by this user fee. As in benefit years 2014 through 2020, issuers seeking to participate in an FFE in the 2021 benefit year will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP.

a. FFE User Fee Rate

For the 2021 benefit year, issuers participating in an FFE will receive special benefits from the following Federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and

- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Activities through which FFE issuers receive a special benefit also include the Health Insurance and Oversight System (HIOS) and Multidimensional Insurance Data Analytics System (MIDAS) platforms, which are partially funded by Exchange user fees. Based on estimated costs, enrollment (including changes in FFE enrollment resulting from anticipated establishment of State Exchanges or SBE–FPs in certain states in which FFEs currently are operating), and premiums for the 2021 plan year, we solicited comment on two alternative proposals. First, we proposed maintaining the FFE user fee for all participating FFE issuers at 3.0 percent of total monthly premiums in order to preserve and ensure that the FFE has sufficient funding to cover the cost of all special benefits provided to FFE issuers during the 2021 benefit year.

We also solicited comment on an alternate proposal that would reduce the FFE user fee rate below the 2020 benefit year level. As discussed in the proposed rule, the alternative proposal reflected our estimates of premium increases and enrollment decreases for the 2021 benefit year, as well as potential savings resulting from cost-saving measures implemented over the last several years that we expect would enable HHS to collect user fees at a lower rate, thereby reducing the user fee burden on consumers and creating downward pressure on premiums, while still fully funding FFE operations. As discussed in the proposed rule, if these savings did not materialize, we would have increased user fee rates for the subsequent benefit year, to ensure that sufficient funds would be available to cover the costs of special benefits provided to FFE issuers. We solicited comment on this proposal. We also solicited comment on trends in usage of Exchange functions and services, potential efficiencies in Exchange operations, and premium and enrollment projections, all of which might inform a change in the user fee rate in the final rule. We did not receive any comments on the trends in usage of Exchange functions and services, potential efficiencies in Exchange operations, and premium and enrollment projections.

b. SBE–FP User Fee Rate

As previously discussed, OMB Circular No. 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. SBE-FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and Federal programs. Accordingly, in § 156.50(c)(2), we specify that an issuer offering a plan through an SBE-FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, unless the SBE-FP and HHS agree on an alternative mechanism to collect the funds from the SBE-FP or state. The benefits provided to issuers in SBE-FPs by the Federal Government include use of the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, as defined at section 1413(e) of the PPACA, and QHP enrollment functions under § 155.400. The user fee rate for SBE-FPs is calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE-FPs.

We proposed a user fee rate of 2.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE-FP. Similar to our proposal to maintain the FFE user rate applicable to benefit year 2020, maintaining the SBE-FP user rate at 2.5 percent of premium would result in stability in the amount of user fees collected.

We also considered and solicited comment on an alternate proposal that would lower the SBE-FP user fee rate below the 2020 benefit year level to a level that would reduce the user fee burden on consumers, while still covering the costs of the special benefits HHS provides to SBE-FP issuers. We discussed that we will continue to examine contract cost estimates for the special benefits provided to issuers offering QHPs on the Exchanges using the Federal platform for the 2021 benefit year as we finalize the FFE and SBE-FP user fee rates. We solicited comment on the alternative proposal.

In addition, we solicited comment on trends in usage of Federal platform functions and services, potential

efficiencies in Federal platform operations, and premium and enrollment projections, all of which might inform a change in the user fee level in the final rule.

After reviewing the public comments, we are finalizing the proposed rates of 3.0 percent for the FFE user fee rate and 2.5 percent for the SBE-FP user fee rate for the 2021 benefit year.

The following is a summary of the public comments we received.

Comment: A group of commenters supported lowering user fee rates only if the reduction would not adversely affect FFE operations. Another group of commenters supported maintaining current user fee rates in favor of HHS re-investing excess user fees into consumer outreach and education activities, the improvement of *HealthCare.gov*, or otherwise increasing funding of these activities to 2017 levels. One commenter recommended HHS spend additional funding on providing additional in-language resources for those with limited English proficiency.

Response: We are finalizing user fee rates at 3.0 percent for FFE issuers and 2.5 percent for SBE-FP issuers, which is the same as the user fee rates for the 2020 benefit year. These user fees will provide ample funding for the full functioning of the Federal platform. Based on projected changes in costs, enrollment and premiums, we project that we can readily fund Federal platform costs associated with providing special benefits to these issuers. HHS remains committed to providing a seamless enrollment experience for consumers who enroll in coverage through an Exchange that uses the Federal platform. We will continue to apply resources to cost-effective, high-impact outreach and marketing activities that offer the highest return on investment. Thus, we are not committing to increasing funding for outreach and education activities in excess of current levels or to levels similar to those that existed in prior years, but we will continue to evaluate consumer outreach and education needs within the normal annual budget process. Consistent with OMB Circular No. A-25, any collections in excess of user fee-eligible costs for a given year will be rolled over for spending on the subsequent year's user fee-eligible expenses.

Comment: Some commenters expressed support for lower user fee rates for issuers participating in Enhanced Direct Enrollment (EDE), or who take on additional administrative functions.

Response: While we expect long-term economies of scale and cost reductions

associated with EDE, HHS incurs costs associated with building, maintaining and improving the infrastructure associated with EDE. However, we will continue to review the costs associated with EDE and potential interactions between EDE implementation and user-fee eligible costs.

Comment: One commenter suggested that HHS lower the SBE-FP user fee rate to 1.5 percent for SBE-FPs for several reasons. The commenter stated that SBE-FP states can take on federal tasks, such as eligibility and enrollment processes, Navigator and agents programs, and consumer selection tools. The commenter also stated that call centers can be reduced since most enrollments are automatic re-enrollments, and the Federal Platform and call center tasks can be taken on by issuers. Further, the commenter stated that the Exchanges are not to the benefit of the issuers, since there is no competitive advantage to being on the Exchanges, the existence of the Exchanges are mandated by law, and the benefits associated with user fees are all to the consumers, and not the issuers who pay them.

Response: We calculated the SBE-FP user fee rate based on the proportion of all FFE functions that are also conducted for SBE-FPs. The final SBE-FP user fee rate for the 2021 benefit year of 2.5 percent of premiums is based on HHS's calculation of the percent of costs of the total FFE functions utilized by SBE-FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, which we estimate to be approximately 85 percent. As described in this rule, user fee eligible cost estimates are reviewed on an annual basis and developed in advance of the benefit year. Setting the SBE-FP user fee rate below the proportion of costs associated with benefits provided to SBE-FP issuers would result in FFE QHPs subsidizing the functions used by QHPs in SBE-FPs.

Comment: Several commenters asked HHS to provide more data and transparency into how user fee rates are calculated.

Response: The FFE and SBE-FP user fee rates for the 2021 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE-FPs, and evaluation of expected enrollment and premiums for the 2021 benefit year. Annually, HHS and CMS also publish detailed information on Federal Exchange Activities and budget request estimates,

including expected Exchange user fee eligible costs.¹²²

User fee eligible costs are estimated in advance of the benefit year and are based upon cost targets for specific contracting activities that are not yet finalized, and therefore proprietary. We will continue to outline user fee eligible functional areas in the annual Payment Notices, and will evaluate contract activities related to operation of the federal Exchange user fee eligible functions. The categories that are considered user fee eligible include activities that provide special benefits to issuers offering QHPs through the Federal platform, and do not include activities that are provided to all QHP issuers. For example, functions related to risk adjustment program operations and operations associated with APTC calculation and payment, which are provided to all issuers in states where HHS operates the risk adjustment program (all 50 states and the District of Columbia for the 2021 benefit year), are not included in the FFE or SBE-FP user fee eligible costs. However, costs related to Exchange-related information technology, health plan review, management and oversight, eligibility and enrollment determination functions including the call center, and consumer information and outreach are considered FFE user fee eligible costs. SBE-FPs conduct their own health plan reviews and consumer information and outreach, and therefore, the SBE-FP user fee rate is determined based on the portion of FFE costs that are also applicable to issuers offering QHPs through SBE-FPs.

3. 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 to amend § 156.111 to require states each year, beginning in plan year 2021, to identify required benefits mandated by state law and which of those benefits are in addition to EHB in a format and by a date specified by HHS. If the state does not comply with this annual reporting submission deadline, we proposed that HHS will determine which benefits are in addition to EHB for the state. We are finalizing the annual reporting of state-required benefits policy as proposed, with minor revisions. We are also

finalizing as proposed that the first annual submission deadline for states to notify HHS of their state-required benefits will be July 1, 2021.

Section 1311(d)(3)(B) of the PPACA 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. In the EHB final rule,¹²³ we finalized a standard at § 155.170(a)(2) that specifies benefits mandated by state action taking place on or before December 31, 2011, even if not effective until a later date, may be considered EHB, such that the state is not required to defray costs for these state-required benefits. Under this policy, benefits mandated by state action taking place after December 31, 2011 are considered in addition to EHB, even if the mandated benefits also are embedded in the state's selected EHB-benchmark plan. In such cases, states must defray the associated costs of QHP coverage of such benefits, and those costs should not be included in the percentage of premium attributable to coverage of EHB for purpose of calculating APTC.

We also finalized in the EHB final rule that, because the Exchange is responsible for certifying QHPs, the Exchange would be the entity responsible for identifying which additional state-required benefits, if any, are in addition to the EHB. We also finalized that it is the QHP issuer's responsibility to quantify the cost attributable to each additional required benefit based on an analysis performed in accordance with generally accepted actuarial principles and methodologies conducted by a member of the American Academy of Actuaries and to then report this to the state. Although § 155.170 contemplates issuers conducting the cost analysis independently from the state, we now clarify that it would also be permissible for issuers to choose to rely on another entity, such as the state, to produce the cost analysis, provided the issuer remains responsible for ensuring that the quantification has been completed in a manner that complies with § 155.170(c)(2)(i) through (iii).

We also finalized that this calculation should be done prospectively to allow for the offset of an enrollee's share of premium and for purposes of calculating the PTC and reduced cost

sharing. We reminded states and issuers that 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 a PTC. We also finalized that because states may wish to take different approaches with regard to basing defrayal payments on either a statewide average or each issuer's actual cost that we were not establishing a standard and would permit both options for calculating state payments, at the election of the state. As discussed in the proposed rule, we clarified that we interpret actual cost to refer to the actuarial estimate of what part of the premium is attributable to the state-required benefit that is in addition to EHB, which is an analysis that should be performed prospectively to the extent possible.

In the 2017 Payment Notice,¹²⁴ we clarified that section 1311(d)(3)(B) of the PPACA governing defrayal of state-required benefits is not specific to state statutes and we thus interpreted that section to apply not only in cases of legislative action but also in cases of state regulation, guidance, or other state action. We also finalized a change to § 155.170(a)(3), designating the state, rather than the Exchange, as the entity required to identify which benefits mandated by state action are in addition to EHB and require defrayal. We also clarified in the 2017 Payment Notice¹²⁵ that there is no requirement to defray the cost of benefits added through supplementation of the state's base-benchmark plan, as long as the state is supplementing the base-benchmark to comply with the PPACA or another Federal requirement. We also explained in the 2017 Payment Notice that this means benefits mandated by state action after December 31, 2011 for purposes of compliance with new Federal requirements would not require defrayal. Examples of such Federal requirements include: requirements to provide benefits and services in each of the ten categories of EHB; requirements to cover preventive services; requirements to comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA); and the removal of discriminatory age limits from existing benefits.

In the 2017 Payment Notice, we also affirmed a transitional policy originating from the 2016 Payment Notice,

¹²² FY2021 CMS Budget Request is available at <https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/FY2021-CF-Final.pdf>, and FY2021 HHS Budget Request is available at <https://www.hhs.gov/sites/default/files/fy-2021-budget-in-brief.pdf>.

¹²³ Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 FR 12834, 12837 through 12838 (February 20, 2013), available at <https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

¹²⁴ 81 FR at 12242.

¹²⁵ This was originally clarified in the 2016 Payment Notice, and reiterated in the 2017 Payment Notice.

specifying that § 156.110(f) allows states to determine services included in the habilitative services and devices category without triggering defrayal if the state's base-benchmark plan does not include coverage for that category. We interpreted this to mean that, when a state has an opportunity to reselect its EHB-benchmark plan, a state may use this as an opportunity to also update its habilitative services category within the applicable Federal parameters for doing so as part of EHB-benchmark plan reselection. As such, once a state has defined its habilitative services category under § 156.110(f), state-required benefits related to habilitative services may trigger defrayal in accordance with § 155.170 if they are in addition to EHB and/or outside of an EHB-benchmark plan selection process.

In the 2019 Payment Notice,¹²⁶ we finalized that, as part of the new EHB-benchmark plan selection options for states at § 156.111, we would not make any changes to the policies governing defrayal of state-required benefits at § 155.170. That is, whether a benefit mandated by state action could be considered EHB would continue to depend on when the state enacted the mandate (unless the benefit mandated was for the purposes of compliance with Federal requirements). We reminded states of their obligations in light of the new EHB-benchmark plan selection options for states at § 156.111 in an October 2018 FAQ.¹²⁷ In this FAQ, we also reminded states that, although it is the state's responsibility to identify which state-required benefits require defrayal, states must make such determinations using the framework finalized at § 155.170. For example, a law requiring coverage of a benefit passed by a state after December 31, 2011, is still a state-required benefit requiring defrayal even if the text of the law says otherwise. We affirmed that in the proposed rule. We also noted that we are monitoring state compliance with the defrayal requirements regarding state-required benefits in addition to EHB at § 155.170, and that we encouraged states to reach out to us concerning any state defrayal questions in advance of passing and implementing benefit mandates.

As explained in the proposed rule, HHS is concerned that there may be states that are not defraying the costs of the state-required benefits in accordance with federal requirements. State

noncompliance with section 1311(d)(3)(B) of the PPACA, as implemented at § 155.170, may result in an increase in the percent of premium that QHP issuers report as attributable to EHB, more commonly referred to as the "EHB percent of premium," which is used to calculate PTCs. Due to state noncompliance with defrayal of state-required benefits, issuers may be covering benefits as EHB that were required by state action after December 31, 2011 that actually require defrayal under federal requirements, but for which the state is not actively defraying costs. As such, to strengthen program integrity and potentially reduce improper federal expenditures, we proposed to amend § 156.111(d) and to add a new § 156.111(f) to explicitly 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 and/or small group market that are considered to be "in addition to EHB" in accordance with § 155.170(a)(3). Given the proposed changes, we further proposed to rename § 156.111 "State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020, and annual reporting of state-required benefits" to better reflect its contents.

After reviewing and carefully considering the comments, we are finalizing these policies at § 156.111(d) and (f), but with changes explained below. We are also finalizing the revision of the heading of § 156.111 so that it accurately describes the new requirements in this final rule.

Comment: Most commenters objected to the proposed annual reporting policy as unnecessary and without adequate justification, asking that we withdraw the proposed changes entirely. A minority of commenters supported the proposed changes, supporting the observation that states have not been defraying state benefit requirements consistently. Supporting commenters agreed that requiring states to report their state benefit requirements to HHS would improve transparency and accountability of states that may not be appropriately defraying the costs of state benefit requirements in addition to EHB and that this reporting policy will help to ensure that Exchange subsidies are calculated and used appropriately.

Commenters objecting to the proposed policy stated that HHS did not provide sufficient evidence that states are not complying with federal defrayal requirements, and that HHS should first develop a strong evidentiary basis that states are not properly compensating issuers or enrollees for state-required

benefits in addition to EHB before imposing onerous new requirements on states. Several commenters explained that, contrary to HHS's concerns expressed in the proposed rule, states are already regularly making careful assessments about whether their state benefit requirements are in addition to EHB and are doing so in accordance with federal requirements. One commenter noted that its state has coordinated a robust inter-agency process since 2013 to comply with section 1311 of the PPACA and defrayed the cost of state benefit requirements in addition to EHB since 2014. This commenter urged HHS to withdraw the proposal, expressing that finalization would be disruptive and unnecessary to states such as its own which have already set up a fully functional process. Other commenters noted that this reporting requirement is unnecessary given that we already publish information about state benefit requirements on the CMS website.

Commenters opposing the reporting policy as unnecessary also stated that existing regulations already establish robust requirements for states and issuers to follow when a state benefit requirement is in addition to EHB and requires defrayal, including performing actuarially sound analyses of costs associated with state benefit requirements in addition to EHB when calculating APTCs. Commenters also noted that HHS already has existing authority to investigate states that are not complying with defrayal requirements and that, as such, imposing a reporting requirement on states is not necessary for federal oversight purposes.

Many commenters also opposed the annual reporting policy because it would be an additional administrative burden on states, the type this administration instructed agencies to reduce to the maximum extent permitted by law. They also noted the burden states already bear as the entities responsible for identifying which mandates require defrayal. One commenter recommended that HHS leverage existing reporting related to EHB rather than creating a new, duplicative report, though the commenter did not provide clarity on what reporting this is. One commenter stated that HHS making determinations in the state's place about which state-required benefits are in addition to EHB conflicts with Executive Order 13865, "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients," which directs HHS "to the maximum extent permitted

¹²⁶ 83 FR 16930, at 16977.

¹²⁷ Frequently Asked Questions on Defrayal of State Additional Required Benefits (October 2018), available at <https://www.cms.gov/CIOO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-Defrayal-State-Benefits.pdf>.

by law, provide relief from any provision or requirement of the PPACA that would impose a fiscal burden on any State. . . .”¹²⁸ Commenters also expressed concern that the annual reporting requirement will be so burdensome that it will discourage states from adopting changes to provide additional health benefits to consumers or even deter states from updating their EHB-benchmark plan.

Response: We continue to have concerns that states are not defraying the costs of their state-required benefits in addition to EHB in accordance with federal requirements. As a result of this noncompliance, 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. This contravenes section 36B(b)(3)(D) of the Code, which specifies that the portion of the premium allocable to state-required benefits in addition to EHB shall not be taken into account in determining a PTC.

HHS must ensure that APTC is paid in accordance with federal law. We continue to believe that requiring states to annually report their state benefit requirements to HHS will strengthen program integrity in this regard.

We note that, contrary to some commenters’ assertions, we do not currently collect detailed information from states with regard to their state benefit requirements. We therefore do not have an existing means of assessing whether states are complying with federal defrayal requirements or whether federal APTC payments are properly allocated solely to EHB. The “State-Required Benefits” links listed under each state on the “Information on Essential Health Benefits (EHB) Benchmark Plans” page on the CMS website¹²⁹ are not actively updated by the states or by HHS. Those records of state benefit requirements were collected in conjunction with state updates to EHB-benchmark plans in 2015 for plan years beginning in 2017. Furthermore, we do not collect detailed information about state-required benefits when states update their EHB-benchmark plans pursuant to the new flexibility we finalized at

§ 156.111(a).¹³⁰ Therefore, our records are outdated by several years and do not reflect the most current information about state benefit requirements in addition to EHB, nor do they contain the level of detail we will collect as part of the annual reporting requirement we are finalizing here.

State submissions of annual reports on state-required benefits will enable HHS to determine whether HHS is paying APTC correctly. The information states submit will provide the necessary information to HHS for increased oversight over whether states are appropriately identifying which state benefit requirements are in addition to EHB and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs.

We acknowledge that some states may already be appropriately identifying which state-required benefits are in addition to EHB and require defrayal, and that these states may have developed processes for defraying these state-required benefits. However, other states may not be doing so. This annual reporting policy will assist in achieving greater compliance with § 155.170 in all states, which will help to resolve HHS’s current program integrity concerns.

Furthermore, we disagree that requiring already compliant states to annually report would be disruptive and unnecessary. 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 required to be reported to HHS. This reporting requirement should be complementary to the process the state already has in place for tracking and analyzing state-required benefits. We also note that this regulation provides 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 the state-mandated benefits it believes are in addition to EHB for the applicable plan year. HHS prefers for states to provide the required information on their state-required benefits to support

HHS’s efforts to determine whether it is paying APTC correctly. However, if states choose not to provide this information in accordance with § 156.111(d) and (f), HHS must rely on its own ability to assess the scope of EHB in that state to ensure that only proper federal expenditures of APTC are made by the federal government.

Finalizing an annual reporting requirement for states to provide information regarding their state benefit requirements to HHS properly aligns with federal requirements for defraying the cost of state-required benefits; will generally improve transparency with regard to the types of benefit requirements states are enacting; and will provide 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.

Therefore, we are finalizing § 156.111(d) and (f) as proposed, to require states to annually notify HHS of any state-required benefits applicable to QHPs in the individual and/or small group market that are considered to be “in addition to EHB” in accordance with § 155.170(a)(3). We are also finalizing as proposed that the first annual submissions deadline for states to notify HHS of their state-required benefits in accordance with § 156.111(d) and (f) will be July 1, 2021.

Comment: One commenter stated that HHS should make the determination about which benefits require defrayal in every instance, because relying on the state’s determination does not provide adequate program integrity. All other commenters on this topic stated we should retain § 155.170(a)(3) as is, designating the state as the entity responsible for identifying which mandates are in addition to EHB because they believe states are best positioned to make these determinations. Some commenters opposed any change making the Exchange or HHS the entity responsible for making such determinations, even in instances where the state does not submit an annual report to HHS by the annual reporting deadline or does not do so in the form and manner specified by HHS. Commenters stated that states should be able to continue their own processes for reviewing and defraying state-mandated benefits, and that to require otherwise would be disruptive and unnecessary, especially in states that have set up an already complete process for making these determinations and defraying costs when necessary.

¹²⁸ Executive Order 13865, “Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients,” 82 FR 26885, 26886 (June 12, 2017) available at <https://www.govinfo.gov/content/pkg/FR-2017-06-12/pdf/2017-12130.pdf>.

¹²⁹ Information on Essential Health Benefits (EHB) Benchmark Plans available at <https://www.cms.gov/cciio/resources/data-resources/ehb>.

¹³⁰ If a state chooses to utilize the flexibility finalized at § 156.111(a) to select a new EHB-benchmark plan starting with the 2020 plan year, we currently only ask the selecting state if the EHB-benchmark plan includes benefits mandated by state action taking place after 2011, other than for purposes of compliance with Federal requirements, for which payment is required under § 155.170. For more information, please refer to the State Confirmation Template in the information collection currently approved under OMB control number: 0938-1174 (Essential Health Benefits Benchmark Plans (CMS-10448)).

Commenters stated that shifting authority away from the state as the entity responsible for making these determinations would be inconsistent with the administration's goals of promoting state flexibility. For example, one commenter stated that HHS's identification of state-required benefits that are in addition to EHB conflicts with Executive Order 13865, "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients." That Executive Order directs HHS, "to the maximum extent permitted by law, to afford the States more flexibility and control to create a more free and open health care market. . . ." ¹³¹ One commenter noted that state insurance regulation and oversight dates back to the 1800s, has been recognized by Congress in the McCarran Ferguson Act, ¹³² and that the Supreme Court has also recognized states being the primary regulators of insurance.

Commenters also stated that shifting authority away from the state would be inconsistent with HHS deference to states in other areas of EHB policy. Commenters explained that the EHB-benchmark plan selection process appropriately relies on state choices to set the EHBs under federal guidelines and that, as the primary regulators of individual and small group markets, states should continue to maintain the authority to mandate certain benefits in those markets and are the best positioned entities to determine which, if any, mandated benefits are in addition to EHB. One commenter also noted that defrayal determinations necessarily rely to some extent on state interpretation and judgment. Commenters stated it would be counterproductive for HHS to offer the tremendous increase in state flexibility offered through the new EHB-benchmark plan selection options finalized at § 156.111, only to take unprecedented federal control over another aspect of EHB in the near future. Commenters emphasized that allowing states to continue their own processes supports the administration's general approach of deference to states and their expertise in local market issues. Commenters also stated that HHS does not have expertise in evaluating state-mandated benefit laws and enforcing state requirements.

One commenter also stated that HHS's identification of state-required benefits that are in addition to EHB when a State chooses not to do so is internally inconsistent because § 155.170(a)(3) establishes the state's right to identify which state-mandated benefits are in addition to the EHB. This commenter therefore questioned how HHS acting in the state's place would be consistent with § 155.170(a)(3).

Response: We agree that states are uniquely positioned to track and analyze state-required benefits and identify which state benefit requirements are in addition to EHB and require defrayal. State expertise about the unique legislative and regulatory framework involving proposing, enacting, and implementing state benefit requirements is the reason we also believe states are best situated to populate and submit the proposed annual report, which will serve as documentation for states, issuers, the federal government, and the general public of the state benefit requirements that are in addition to EHB.

We note that the annual reporting policy we are finalizing at § 156.111(d) and (f) does not restrict the state's ability to mandate any particular benefit—it merely requires states to report these state actions to HHS in order to assist in ensuring that HHS is not paying APTC for portions of premiums attributable to non-EHB.

We disagree that § 156.111(d)(2) conflicts with the flexibility offered to states as part of the new EHB-benchmark plan selection process finalized at § 156.111. We believe the annual reporting policy we are finalizing is consistent with this goal of state flexibility and acknowledges state expertise. In the 2019 Payment Notice, we finalized that, as part of the new EHB-benchmark plan selection options for states finalized at § 156.111, we would not make any changes to the policies governing defrayal of state-required benefits at § 155.170. Therefore, whether a benefit mandated by state action can be considered EHB continues to depend on when the state enacted the mandate (unless the benefit mandated was for the purposes of compliance with federal requirements). ¹³³ Under any of the three methods for a state to select a new EHB-benchmark plan at § 156.111, the act of selecting a new EHB-benchmark plan does not alone create new state mandates, but it also does not relieve the state of its obligation to continue defraying the cost of QHPs covering any state-mandated benefits that are in addition to EHB. The annual reporting policy we are finalizing at § 156.111(d)

and (f) does not change that standard. In other words, although states will be required to provide HHS with additional information with regard to state-required benefits, the annual reporting policy itself does not affect whether a state benefit requirement is or is not in addition to EHB.

States are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of those benefits, and states should already be complying with this requirement regardless of the annual reporting policy and regardless of the EHB-benchmark plan selection options at § 156.111.

Although there may be states that do not currently have in place an effective process for tracking, analyzing, and identifying state-required benefits for purposes of identifying whether they are in addition to EHB and require defrayal, all states should be able to readily track, analyze, and identify the requirements they themselves have established. For such states, the annual reporting policy may restrict perceived flexibility in the state to the extent that this annual reporting policy improves the state's compliance with defrayal requirements. However, we believe any such restriction in state flexibility in these otherwise noncompliant states is illusory because states should have already been identifying which benefits require defrayal. Further, we believe that this regulatory change is necessary to ensure that such noncompliant states are diligent about their framework for identifying which mandates are in addition to EHB in accordance with § 155.170 and to ultimately strengthen program integrity and reduce improper federal expenditures.

Finally, the policy does not shift responsibility for identifying whether a mandate is in addition to EHB from the state to HHS, unless the state chooses not to submit an annual report to HHS in accordance with § 156.111(d) and (f). Thus, this policy adds flexibility for states since HHS will identify required benefits that are in addition to EHB only where the state opts not to do so.

Therefore, we are finalizing the proposal with only a minor revision. We originally proposed at § 156.111(d)(2) that for states that do not report to HHS by the annual submission deadline in accordance with § 156.111(d) and (f), HHS would determine which benefits are in addition to EHB consistent with § 155.170(a)(3). We agree with the commenter, however, that referring back to § 155.170(a)(3) is inappropriate because that subsection requires the state, not HHS, to identify which state-required benefits are in addition to the

¹³¹ Executive Order 13865, "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients," 82 FR 26885, 26886 (June 12, 2017) available at <https://www.govinfo.gov/content/pkg/FR-2017-06-12/pdf/2017-12130.pdf>.

¹³² 15 U.S.C. 1011–1015.

EHB. We are thus finalizing a revision such that § 156.111(d)(2) refers instead to § 155.170(a)(2). Section 155.170(a)(2) specifies that benefits required by state action taking place on or before December 31, 2011, are considered EHB and benefits required by state action taking place on or after January 1, 2012, other than for purposes of compliance with Federal requirements, are considered in addition to EHB.

Comment: Many commenters expressed concern that HHS is proposing to increase its oversight of state compliance with defrayal requirements when HHS's policy governing which state benefit requirements are in addition to EHB is still unclear. Commenters also stated that HHS has not codified or formally clarified comprehensive standards that states must use, or that HHS would use under § 156.111(d)(2) to determine whether a state mandate is in addition to EHB and subject to defrayal. Commenters stated that, in the past, HHS has provided subregulatory guidance and verbal technical assistance about defrayal upon which states have relied, and upon which HHS should confirm states can still rely. Commenters also expressed concern that, because much of this guidance provided by HHS was unpublished or vague, HHS interpretation of defrayal policy could have since changed without warning to states, and therefore, states could be subject to unexpected defrayal costs as part of the finalized annual reporting policy. Commenters added that, although HHS provides technical assistance to states regarding what would be considered a state-required benefit in addition to EHB, states have understood these discussions to be examples rather than exhaustive or binding guidance. Commenters urged HHS that further clarifying its defrayal policies is integral for states and legislatures to make fully informed decisions about the consequences of state-required benefits on the state budget. Due to this perceived lack of clarity, commenters urged HHS to not finalize the proposal, but to clarify its defrayal policies and engage in a structured discussion with states to address defrayal questions. These commenters stated that only then should HHS consider issuing more detailed guidance that can be provided uniformly to states moving forward. One commenter recommended that, if this provision is finalized, HHS delay the implementation of an annual reporting requirement and instead take additional time to determine how many states are not complying with defrayal

requirements so that HHS can better understand the scope of the problem the reporting policy is intended to address.

Several commenters offered specific policy recommendations about how HHS should modify its current policy on whether a state benefit requirement is in addition to EHB.

Response: We acknowledge commenters' concerns that they do not fully understand when a state-required benefit is in addition to EHB and requires defrayal. However, finalizing an annual reporting policy is important to help resolve HHS's program integrity concerns regarding improper federal expenditures of APTC for benefits that are in addition to EHB. The information states provide to HHS in the annual reports will assist HHS in identifying whether states are appropriately identifying which state-required benefits require defrayal, and therefore, whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs.

In addition to the existing guidance we have provided on defrayal through our past regulations and guidance documents, we intend to continue to engage with states and provide additional technical assistance that helps ensure state understanding of when a state-benefit requirement is in addition to EHB and requires defrayal. We anticipate that this assistance will provide examples and explains how a state could operationalize the defrayal process pursuant to federal requirements at § 155.170. We 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.

While we appreciate commenters' recommendations on how HHS should modify its current policy on whether a state benefit requirement is in addition to EHB, such recommendations are outside the scope of this rulemaking, which is limited to reporting of state benefit requirements.

Comment: Several commenters raised concerns that this rule does not specify how HHS will use the information states provide in the annual reports and does not outline what oversight activities HHS will conduct. Commenters urged HHS to provide additional transparency into how it will use state reported information on benefit requirements to enhance its oversight and enforcement of § 155.170. For example, one commenter suggested HHS clarify how it will review state information from state actions taken prior to the first annual reporting submission deadline

and clarify whether HHS will take retroactive action to determine if previous state benefit requirements are in addition to EHB and require defrayal. Several commenters stated that the annual reports should only be used to hold states accountable prospectively for defrayal of state benefit requirements in addition to EHB, and that it would be of great concern to states if HHS's intention is to review annual reports for retrospective compliance with defrayal, which would have significant practical consequences.

Other commenters stated that HHS should enhance the already existing oversight that would occur if the policy is finalized as proposed, by developing and providing details on how it intends to ensure that states' annual reports are accurate and complete, for example through annual audits of state reports, and requested specific information regarding whether HHS will review the reports for prior state activity. One commenter suggested that HHS require "one source of truth" as to which benefit requirements in a given state are in addition to EHB and require defrayal so that QHP issuers can be sure they have the correct benefits listed as EHBs.

Many commenters requested that, before the reporting requirement is finalized, states understand the potential liabilities the reported information could generate (for example, types of remedial action). Commenters argued that, although section 1311(d)(3)(B) of the PPACA requires states defray the cost of benefits in addition to EHB to either the enrollee or the issuer on behalf of the enrollee, it does not provide a process for how an HHS determination about a state's benefit requirement can substitute the state's own policy conclusion with regard to whether that benefit requirement is in addition to EHB. Commenters argued that section 1311(d)(3)(B) of the PPACA does not give HHS authority to interpret state insurance law. Commenters also requested that HHS clarify the process for when HHS reviews a state's annual report, or makes the determination for a non-reporting state, and the state disagrees with HHS or otherwise refuses to comply with HHS's determination and does not defray the cost of the state benefit requirement that HHS believes is in addition to EHB. One commenter stated that it is not clear what options exist in the event of conflict except for HHS to overrule the will of state legislative and executive branches, state insurance commissioners' authority, and Exchanges' state-based authority.

Commenters argued that HHS must establish a neutral and fair process for

evaluating state-mandated benefits and resolving disputes between HHS and the state. For example, one commenter stated that there needs to be a formal appeals process because HHS has a conflict of interest in determining whether a mandate requires defrayal since such a determination could potentially lower the amount of APTC the government needs to pay out, and therefore, this proposal is arbitrary and capricious without a formal hearing or appeals process. Other commenters expressed concern that there was no proposed dispute resolution or appeals process, especially since the remedial action HHS would take is unclear.

Commenters recommended that federal oversight and compliance actions over state benefit requirements reported in the annual reports remain limited and that retaining the primary authority with the states will help avoid circumstances of conflict between the state and HHS about whether a benefit requirement is in addition to EHB. One commenter stated that there would be far reaching operational problems if HHS incorrectly issues a decision about a state benefit requirement because that interpretation would interfere with state form review, rate review, plan certification, market conduct exams, enforcement, and even consumer assistance. Another commenter understood the proposal to mean that HHS could also determine the amount to be defrayed by the state for a benefit that is in addition to EHB. This commenter stated they are unaware of any authority that would allow the federal government to access and spend money from a state's treasury.

Many commenters questioned whether HHS has any available enforcement authority to actually require states to defray the cost of a state benefit requirements in such situations of disagreement between the state and HHS. Commenters stated that there is no legal mechanism in place for resolving any disputes HHS may have with a state's determination which calls into question the very need for the amendments to § 156.111, if HHS has no viable enforcement authority.

One commenter was critical that the proposed rule did not specify what the procedure would be for direct enforcement states that do not report to HHS. The same commenter argued that HHS making the determinations about which state benefit requirements are in addition to EHB and require defrayal would be unconstitutional commandeering of states, and would violate the Tenth Amendment because it coerces states to act. Commenters noted that, different from the authority HHS

has to implement federal law in states that refuse or are unable to, in this case HHS is giving itself authority to interpret state insurance law, which is authority that neither the PPACA nor other laws related to health insurance provide to HHS. This commenter stated that the PPACA requirement to defray is unconstitutional in the first place and that HHS should not seek through this rulemaking to further attempt to implement this unconstitutional requirement. This commenter further stated they are uncertain whether the federal government can compel a direct enforcement state to pay a part of anyone's insurance premium or even any portion of federal subsidies.

Response: We acknowledge the discomfort expressed by some commenters with regard to how HHS intends to use the information included in the annual reports for oversight purposes, especially given commenters' stated concerns regarding lack of clarity about the defrayal policy itself, and how to identify whether a state benefit requirement is in addition to EHB. However, we believe that conducting additional technical assistance to states in the interim will assist in easing state concerns and uncertainty about identifying which state benefit requirements are in addition to EHB and require defrayal.

We further acknowledge that some states already comply with § 155.170, making reasoned assessments about state benefit requirements, and defraying benefits in addition to EHB. Nonetheless, we still believe collecting annual reports for such states is necessary. We also believe collecting annual reports from otherwise compliant states will improve transparency generally with regard to the types of benefit requirements states are enacting.

HHS will review the information states submit in their reports to help determine whether HHS is paying APTC correctly. Without such reports, HHS lacks the information necessary to make these assessments. Although all information submitted in the reports will be helpful to HHS, we anticipate most closely reviewing the information the state provides pursuant to § 156.111(f)(2) and (3), regarding whether a state-required benefit is or is not in addition to EHB and the basis the state provides for why a state-required benefit is not in addition to EHB. To the extent that HHS has concerns about the content of a state's annual report, or has concerns about a non-reporting state's compliance with HHS's identification of which state benefit requirements are in addition to EHB and require defrayal,

HHS intends to first reach out to the state directly to resolve any such concerns.

To the extent possible, it is our intent to continue the collaborative process we have cultivated with states up to this point regarding questions states have about defrayal. We continue to believe states are best suited to analyze their own state mandates, which is why we are finalizing the annual reporting policy in a manner that relies first on states to submit information to HHS identifying which state-required benefits are in addition to EHB. We also are finalizing that HHS will identify, rather than determine, which benefits are in addition to EHB in states that opt not to report. We note that, as finalized, the annual reporting requirement is the same for all states regardless of whether they are an enforcing or direct enforcement state. We intend to provide non-reporting states with an opportunity to review our identifications prior to releasing the annual reports on the CMS website for public viewing in an effort to mitigate the potential for disagreement between the state and HHS. We also believe our interim outreach with states to clarify defrayal policy more generally will assist in states' understanding on what basis HHS will assess whether state-required benefits are in addition to EHB in non-reporting states.

Further, we disagree with commenters' assertions that HHS does not have enforcement authority to penalize states that refuse to defray the cost of state benefit requirements in addition to EHB in accordance with § 155.170. Pursuant to section 1313(a)(4) of the PPACA, if the Secretary determines that a state or Exchange has engaged in serious misconduct with respect to compliance with requirements under Title I of the PPACA, which includes the requirement that states defray the cost state benefit requirements in addition to EHB, HHS is authorized to rescind up to 1 percent of payments otherwise due to a state per year until corrective actions are taken by the state that are determined to be adequate by the Secretary. HHS would like to avoid the use of such authority, especially as it would not result in a transfer of any portion of such amounts to the issuer or consumer who is entitled to state defrayal payments under the PPACA. We disagree, however, that using this authority would be overstepping HHS authority.

HHS also disagrees that identifying benefits that are in addition to EHB in a state and requiring defrayal violates the Tenth Amendment. We

acknowledge that HHS's identification of state-required benefits that are in addition to EHB might conflict with the opinion of a non-reporting state. However, as previously noted, HHS must ensure that APTC is paid in accordance with federal law. If a state is not defraying the cost of a state-required benefit that is in addition to EHB, resulting in improper federal expenditures, we believe section 1313(a)(4) of the PPACA provides HHS with the authority to enforce the defrayal requirements outlined in statute.

Program integrity remains a top priority for HHS, and we believe exercising our existing authority to address noncompliance with defrayal requirements under section 1311(d)(3)(B) of the PPACA and § 155.170, if necessary, is warranted to mitigate the risk of federal dollars incorrectly leaving the federal Treasury in the form of APTC during the year. However, we appreciate commenters' desire for further insight into how the notices will play into our policy for enforcing the defrayal requirements. We are not 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. The requirement to submit reports under this final rule is independent of a state's pre-existing duty under section 1313(a)(4) of the PPACA to defray costs for state-mandated benefits that are in addition to EHB. Whether we discover noncompliance with defrayal requirements through submission of the reports required under this final rule or through a complaint lodged by a consumer or an issuer, HHS will take appropriate action in line with its statutory authority. However, as noted earlier, we intend to continue the collaborative process we have cultivated with states up to this point. We intend to provide non-reporting states with an opportunity to review our identifications of state-mandated benefits that are in addition to EHB prior to releasing the annual reports on the CMS website for public viewing in an effort to mitigate the potential for disagreement between the state and HHS.

Comment: Commenters noted mixed opinions with regard to a public comment period. Some commenters stated that they do not think it is necessary to allow for a public comment period before publicizing state reporting, but suggested HHS develop a procedure to use in the event there ever is a mistake in a state's mandated benefit reporting. Other commenters

stated there should be a public comment period on the annual reports. Commenters stated that it is important to allow issuers and other stakeholders to provide formal input, and create a public record, on which benefit requirements require defrayal given that states have a conflict of interest in identifying these mandates themselves, and that HHS should review the record of comments when reviewing state-reported benefit mandates as part of its oversight review.

Response: We agree with commenters that it is unnecessary to require a public comment period on the annual reports submitted to HHS or for the annual reports that HHS completes for non-reporting states. State benefit requirements most often originate from the state legislature and, upon passage, the question of whether or not the benefit requirement is in addition to EHB has a fixed answer. As such, the feedback provided to states or HHS from the public or from stakeholders during a public comment period could not impact the ultimate decision on the part of states, or on the part of HHS for non-reporting states, about whether a benefit requirement is in addition to EHB. Therefore, we do not believe a public comment period would be a beneficial use of time or resources.

Comment: Several commenters had specific recommendations or concerns regarding the type of information states would be required to submit to HHS by the annual submission deadline in a form and manner specified by HHS. One commenter requested that, to support the administration's goals of state flexibility, HHS instead allow states to submit state mandate information in a form and manner determined by the state.

Other commenters expressed concern that HHS did not provide sufficient specificity about the types of data elements states would be required to include in the annual report. For example, one commenter stated that there is not enough detail in the proposed rule about how this reporting process would work and HHS should make the proposed templates available for commenters to review. One commenter urged HHS to include information on the final annual reporting templates to be used by states that would identify whether the state benefit requirement doesn't require defrayal because it falls into an exception to the defrayal policy. Another commenter requested that, after the initial report in the first year of annual reporting, states should only identify changes to benefit requirements to make it easier for HHS and issuers to

identify which benefits are new or modified.

One commenter argued that states should also be required to report these additional benefits to the insurance department or other agencies. Another commenter suggested that HHS require states to submit their methodologies for conducting their defrayal analysis to require additional transparency. A different commenter argued that states should not be required to provide a justification or basis for the state's defrayal determination as there is no statutory or regulatory authority for HHS to impose this burden, but that if it finalizes this requirement the commenter agrees such justification should be concise (for example citing to the state constitution amendment that gives the state department of insurance the authority to oversee insurance). One commenter stated that the report should detail the benefits that are included as EHBs in the benchmark plan, state mandated benefits that are part of the benchmark plan, state mandated benefits that are subject to state defrayal, and a list of common benefits that must be considered non-EHB by QHPs.

Response: We appreciate the feedback provided in comments regarding ways to improve the annual reporting process and the data elements that would be most helpful for HHS to collect. We are finalizing as proposed § 156.111(f), which specifies the type of information states are required to submit to HHS by the annual submission deadline in a form and manner specified by HHS. For a reporting package to be complete, it will need to comply with each requirement listed at § 156.111(f)(1) through (6). We believe 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 such that states and other stakeholders reviewing those requirements can understand the scope of the information states are required to include in their annual reports without reviewing the actual reporting templates. With respect to § 156.111(f)(4), which provides for states to submit other information about state-required benefits that is necessary for HHS oversight, we reiterate the illustrative examples we previously published. Additional information that is necessary for HHS oversight may include data such as the date of state action imposing the requirement to cover the state-required benefit; the effective date of the applicable state action; the market it applies to (that is, individual, small group, or both); the

precise benefit or set of benefits that QHPs in the individual and/or small group market are required to cover; any exclusions; and the citation to the relevant state action.

In the first reporting year, this annual report must include a comprehensive list of all state benefit requirements applicable to QHPs in the individual and/or small group market under state mandates that were imposed on or before December 31, 2011 and that were not withdrawn or otherwise no longer effective before December 31, 2011, and any state benefit requirements under state mandates that were imposed any time after December 31, 2011, regardless of whether the state believes they require defrayal in accordance with § 155.170.

The first reporting cycle is intended to set the baseline list of state-required benefits applicable to QHPs in the individual and/or small group market. Each annual reporting cycle thereafter, the state will only be required to update the content in its report to add any new benefit requirements, and to indicate whether benefit requirements previously reported to HHS have been amended or repealed. State reports for subsequent years must be accurate as of 60 days prior to the annual reporting submission deadline set by HHS for that year. If a state has not imposed, amended, or repealed any state benefit requirements in the time period between annual reporting deadlines, the state is still required to report to HHS that there have been no changes to state-required benefits since the previous reporting cycle. In such a scenario, we are finalizing that the state should submit the same reporting package as the previous reporting cycle and affirmatively indicate to HHS that there have been no changes.

As stated in the proposed rule, HHS will provide template(s) reflecting the form and manner of the report that states will be required to use for reporting the required information proposed in § 156.111(f)(1) through (6). We believe standardizing the form and manner of the report and the data elements required is important for consistency year after year and for ensuring HHS has the information necessary to adequately oversee that states are defraying the cost of state-required benefits in addition to EHB consistent with § 155.170 and to ensure that HHS is not improperly paying APTC for portions of premium attributable to non-EHB.

We still intend to post state submissions of these documents on the CMS website prior to the end of the plan year during which the annual reporting

takes place such that this information is accessible to states, QHP issuers, enrollees, stakeholders, and the general public. HHS will complete a similar document for non-reporting states and post it to the CMS website. As noted above, we intend to provide the non-reporting state with an opportunity to review the HHS's identifications prior to posting the HHS-created report on the CMS website. We do not believe it is necessary to explicitly require the state to provide a copy of the report to the insurance department, as the report will be publicly available on the CMS website.

We emphasize that this reporting requirement would be independent of the state's requirement to defray the cost of QHP coverage of state-required benefits in addition to EHB in accordance with § 155.170. 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 under section 1311(d)(3)(B) of the PPACA, as implemented at § 155.170, and would remain fully applicable to states regardless of whether they annually report state-required benefits to HHS or defer to HHS to identify which state-required benefits are in addition to EHB and require defrayal. We also note that issuers would still be responsible for quantifying the cost of these benefits and reporting the cost to the state. States remain responsible for making payments to defray the cost of additional required benefits, either to the enrollee or to the QHP issuer on behalf of the enrollee.

Comment: Many commenters expressed concern with the proposed timing of the annual reporting requirement. Commenters stated that legislative sessions end at different times in different states and that, as such, the annual submission deadline being at the same time during the plan year for every state is not feasible. For example, for states whose legislative sessions end in September, the commenter explained that the proposed reporting deadline in July is too early and would mean the annual reports would include mandates imposed retrospectively rather than prospectively. Another commenter expressed that HHS determinations need to give ample opportunity to states to amend their statutes, be made in advance of rate filings, and only be made on a prospective basis, but that this is impossible given the proposed submission deadline in July. The commenter further explained that their state's legislature adjourns between May 2021 and January 2023, leaving no

ability for the state legislature to legislatively respond to determinations made by HHS under this reporting policy. Many other commenters echoed the request that the annual reporting and defrayal requirements be made only on a prospective basis.

Commenters who supported the entire proposal agreed the reporting should occur annually. One commenter noted their appreciation for the proposal but argued the reporting requirement should be every two years at most to reduce administrative burden and unnecessary costs, given that the process for enacting state mandates is often a long one.

We received no comments on the proposed 60-day cut-off date that proposed to require the annual report be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

Response: As stated in the proposed rule, we acknowledge that the start and end dates of state legislative sessions vary greatly by state, and that many state legislative sessions may not have concluded by the annual reporting submission deadline. However, we believe that setting the same annual submission deadline for all states is necessary to standardize the annual reporting process and publish the annual reports on the CMS website at or around the same time each year. We agree with commenters that we should require reporting annually and that this frequency will best serve HHS's goals of increased oversight over state compliance with defrayal requirements than would a less frequent collection of annual reports.

We also still believe it is important to set a cut-off date after which states are not expected to report on their state-required benefits until the following annual reporting deadline, which is why we are finalizing at § 156.111(f)(1) that state annual reports must be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS. We believe that setting this cut-off date at least 60 days prior to the submission deadline allows a state sufficient time to analyze its state benefit requirements imposed, amended, or repealed through state action taken by that date and prepare the required documents we are proposing that states submit to HHS.

A state where a legislative session ends after the 60-day cut-off date (such as a legislative session that ends in September of that plan year) that happens to enact, amend, or repeal a state-required benefit after the cut-off date but before the annual reporting submission deadline will not be expected to report that state-required

benefit in that plan year's annual reporting submission. Instead, the state is expected to include that state-required benefit in the annual reporting package for the following year. States will be permitted to submit their reports any time between the 60-day cut-off date and the applicable deadline.

We acknowledge commenters' concerns that, depending when the annual reporting submission deadline falls in relation to the state's legislative calendar, the state's annual report may be more reflective of state mandates passed in previous plan years than reflective of the plan year in which the annual reporting submission deadline falls. Although we acknowledge this is not ideal, we do not foresee this being a problem, as the state will be able to include any state-required benefits enacted after the annual submission deadline in the annual reporting package for the following year. Further, we again emphasize that the annual reporting requirement and the reporting cut-off date do not alter a state's obligation to defray the cost of benefits in addition to EHB that result from state action taken after the cut-off date. In other words, states must defray benefits in addition to EHB in accordance with § 155.170 regardless of whether the state benefit requirement was imposed, amended, or repealed through state action taken before or after the proposed 60-day cut-off date for inclusion in that plan year's annual reporting submission. If a state passes a benefit requirement after the annual submission deadline that is in addition to EHB and requires defrayal, the state should defray the cost of that benefit in spite of it not being captured as part of the annual report submitted to HHS for that submission year. The annual reporting requirement should function as an additional, but complementary step to those already in place at § 155.170.

b. States' EHB-Benchmark Plan Options

We proposed May 7, 2021 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year pursuant to § 156.111(a), and the deadline for states to notify us that they wish to permit between-category substitution for the 2023 plan year. We also made some clarifications to § 156.111(b)(2) regarding scope of benefits. We are finalizing these deadlines as proposed and confirming the scope of benefit clarifications.

In the 2019 Payment Notice, we stated that we believe states should have additional choices with respect to benefits and affordable coverage. Therefore, we finalized options for

states to select new EHB-benchmark plans starting with the 2020 plan year. Under § 156.111(a), a state may modify its EHB-benchmark plan by: (1) Selecting the EHB-benchmark plan that another state used for the 2017 plan year; (2) Replacing one or more EHB categories of benefits in its EHB-benchmark plan used for the 2017 plan year with the same categories of benefits from another state's EHB-benchmark plan used for the 2017 plan year; or (3) Otherwise selecting a set of benefits that would become the state's EHB-benchmark plan.

Under any of these three options, the EHB-benchmark plan also has to meet additional standards, including EHB scope of benefit requirements under § 156.111(b). These requirements include providing a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category, the scope of benefits provided under a typical employer plan. Section 156.111(b)(2) defines a typical employer plan as either (1) one of the selecting state's 10 base-benchmark plan options established at § 156.100 from which the state was able to select for the 2017 plan year; or (2) the largest health insurance plan by enrollment in any of the five largest large group health insurance products by enrollment in the selecting state, as product and plan are defined at § 144.103, provided that: (a) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products by enrollment in the selecting state; (b) the plan provides minimum value; (c) the benefits are not excepted benefits; and (d) the benefits in the plan are from a plan year beginning after December 31, 2013. The state's EHB-benchmark plan must also satisfy the generosity standard at § 156.111(b)(2)(ii), which specifies that a state's EHB-benchmark plan must not exceed the generosity of the most generous among a set of comparison plans, including the EHB-benchmark plan used by the state in 2017, and any of the state's base-benchmark plan options for the 2017 plan year, supplemented as necessary.

Additionally, states must document meeting these requirements through an actuarial certification and associated actuarial report from an actuary who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies. We published the "Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with § 156.111(b)(2)(i) and (ii)" (example methodology

guidance), alongside the 2019 Payment Notice.¹³⁴ We finalized that the current EHB-benchmark plan selection would continue to apply for any year for which a state does not select a new EHB-benchmark plan from among these 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. Accordingly, we proposed May 7, 2021 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year. We emphasized that this deadline would be 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 deadline with any questions. Although not a requirement, we recommended states submit applications at least 30 days prior to the submission deadline to ensure completion of their documents by the proposed deadline. We also reminded states that they must complete the required public comment period and submit a complete application by the deadline. We solicited comment on the proposed deadline.

In the 2019 Payment Notice, we also finalized a policy through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that the deadline applicable to state selection of a new benchmark plan would also apply to this state opt-in process. Therefore, we proposed May 7, 2021, as the deadline for states to notify us that they wish to permit between-category substitution for the 2023 plan year. States wishing to make such an election must do so via the EHB Plan Management Community. We solicited comment on the proposed deadline.

We also reiterated the scope of benefits requirements at § 156.111(b)(2). We finalized the definition of a typical employer plan to establish the minimum level of benefits for the state's EHB-benchmark plan selection and to ensure plans that meet EHB standards are equal in scope to a typical employer plan as required under section 1302(2)(A) of the PPACA, and a generosity standard to establish the

¹³⁴ Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii), available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-Example-Acceptable-Methodology-for-Comparing-Benefits.pdf>.

maximum level of benefits for a state's EHB-benchmark plan selection.

The generosity standard at § 156.111(b)(2)(ii) balances our goal of promoting state flexibility with the need to preserve coverage affordability by minimizing the opportunity for a state to select EHB in a manner that would make coverage unaffordable for patients and increase federal costs. As such, we clarified for states that when selecting an updated EHB-benchmark plan from the available options listed at § 156.111(a), the new EHB-benchmark plan may not exceed the generosity of the most generous among the set of comparison plans listed at § 156.111(b)(2)(ii) even by a *de minimis* amount, and that states must clearly demonstrate in their actuarial report to HHS how the state's updated EHB-benchmark plan satisfies the generosity test. In other words, the generosity of the state's updated EHB-benchmark plan may not exceed a 0.0 percentage point actuarial increase above the most generous among the set of comparison plans listed at § 156.111(b)(2)(ii).

Finally, we clarified that the typical employer plan and generosity standard requirements are two separate tests that an EHB-benchmark plan must satisfy. However, we recognized that there may be some instances in which it may be difficult to design an EHB-benchmark plan that satisfies both standards. Therefore, we reminded states that, as we stated in the example methodology guidance,¹³⁵ states should consider using the same plan as the comparison plan for both tests, to the extent possible, to help minimize burden and to mitigate against any potential conflict caused by applying each test with a different comparison plan.

Comment: Multiple commenters agreed with the proposed submission deadlines.

Response: We are finalizing the deadlines as proposed. The deadline for state submission of EHB-benchmark plan changes and to notify HHS that the state will allow between-category benefit substitution for the 2023 plan year is May 7, 2021.

Comment: Some commenters asked for further clarification on the generosity standard when states chose to select a new EHB-benchmark plan. Others did not agree with the generosity standard. One commenter noted that states could interpret the requirement

for a proposed EHB-benchmark plan not to exceed the generosity of the comparison plan to allow a *de minimis* difference in actuarial value. Another commenter stated that the 2019 Payment Notice did not sufficiently emphasize that a state could not exceed the generosity standard.

Response: As provided at § 156.111(e)(2)(ii), the actuary's certification and report must affirm that the state's proposed EHB-benchmark plan does not exceed the generosity of the most generous of the plans listed at § 156.111(b)(2)(i)(A) and (B). Furthermore, "does not exceed the generosity" means that changes to the EHB-benchmark plan cannot result in an increase in generosity beyond that reference plan, no matter how *de minimis*. Finally, when a state selects a new EHB-benchmark plan, the state must, among other requirements, provide an actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms compliance with the generosity standard, consistent with § 156.111(e)(2).

Comment: Several comments were out of the scope of the proposals and pertained to EHB benchmark policy in general. Some commenters noted opposition to the policy previously finalized at § 156.111 in the 2019 Payment Notice. Commenters stated that HHS should ensure that states strictly comply with the requirement to provide public notice and comment on the proposed benchmark plan, including by providing detailed information about proposed changes and the actuarial report that the state must submit to HHS. They also suggested that we implement a federal notice and comment process for state benchmark plan changes. Another commenter noted that the comment period should allow commenters a significant amount of time to respond to the proposal, while another commenter stated that states should notify interested stakeholders when proposing changes to the benchmark. One commenter suggested allowing states to add additional coverage of habilitative services, outside of the process at § 156.111. One commenter urged us to implement a notice and comment process when a state wishes to permit between-category benefit substitution.

Response: As these comments do not pertain to the proposals, we will take them into consideration for future rulemaking. As stated in the 2019 Payment Notice, we expect states to use

a reasonable public comment period.¹³⁶ As a best practice, we encourage states to use the public comment process delineated in any applicable state administrative procedure law or regulations. States must submit a complete application to HHS by the deadline, which means that the state public comment period must have concluded prior to submitting the application to HHS, so that the state can consider public comments prior to submitting the final application.

4. Essential Health Benefits Package (§ 156.130)

a. Premium Adjustment Percentage (§ 156.130)

We proposed to update the 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 the CMS Office of the Actuary. For the 2021 benefit year, the premium adjustment percentage will represent the percentage by which this measure for 2020 exceeds that for 2013.

Section 1302(c)(4) of the PPACA directs the Secretary to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the rate of increase for three parameters detailed in the PPACA: (1) The maximum annual limitation on cost sharing (defined at § 156.130(a)); (2) the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)); and (3) the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code (see section 4980H(c)(5) of the Code). Section 1302(c)(4) of the PPACA and § 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and the regulations provide that this percentage will be published in the annual HHS notice of benefit and payment parameters.

The 2015 Payment Notice¹³⁷ and 2015 Market Standards Rule¹³⁸ 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.

¹³⁶ 83 FR at 17017.

¹³⁷ 79 FR 13743.

¹³⁸ 79 FR 30240.

¹³⁵ Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii), available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-Example-Acceptable-Methodology-for-Comparing-Benefits.pdf>.

Beginning with the 2015 benefit year, the premium adjustment percentage was calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the NHEA. In the proposed 2015 Payment Notice, we proposed that the premium adjustment percentage be calculated based on the projections of average per enrollee private health insurance premiums. Based on comments received, we finalized the 2015 Payment Notice to instead use per enrollee employer-sponsored insurance premiums in the methodology for calculating the premium adjustment percentage. We chose employer-sponsored insurance premiums because they reflected trends in health care costs without being skewed by individual market premium fluctuations resulting from the early years of implementation of the PPACA market reforms. We adopted this methodology in subsequent Payment Notices for the 2016 through 2019 benefit years, but noted in the 2015 Payment Notice that we may propose to change our methodology after the initial years of implementation of the market reforms, once the premium trend is more stable.

In the 2020 Payment Notice, we adopted a modification of the premium measure that we use to calculate the premium adjustment percentage. This premium measure captures increases in individual market premiums in addition to increases in employer-sponsored insurance premiums for purposes of calculating the premium adjustment percentage. Specifically, we calculate the premium measures for 2013 and 2020 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.

This premium measure is an adjusted private individual and group market health insurance premium measure, which is similar to NHEA's private health insurance premium measure. NHEA's private health insurance premium measure includes premiums for employer-sponsored insurance; "direct purchase insurance," which includes individual market health insurance purchased directly by consumers from health insurance issuers, both on and off the Exchanges and Medigap insurance; and the medical portion of accident insurance ("property and casualty" insurance). The measure we used in the 2020 Payment Notice is published by NHEA

and includes NHEA estimates and projections of employer-sponsored insurance and direct purchase insurance premiums, but we excluded Medigap and property and casualty insurance from the premium measure since these types of coverage are not considered primary medical coverage for individuals who elect to enroll. We used per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) so that the premium measure would more closely reflect premium trends for all individuals primarily covered in the private health insurance market since 2013, and we anticipated that the change to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) would additionally reduce Federal PTC expenditures if the Department of the Treasury and the IRS adopted the same premium measure. The Department of the Treasury and the IRS have since adopted the premium growth measure provided in the 2020 Payment Notice for purposes of the indexing adjustments under section 36B of the Code.¹³⁹

We proposed to continue to use the NHEA private health insurance premium measure (excluding Medigap and property and casualty insurance) for the 2021 benefit year. As such, we proposed that the premium adjustment percentage for 2021 be the percentage (if any) by which the most recent NHEA projection of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2020 (\$6,759) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 (\$4,991).¹⁴⁰ Using this formula, the proposed premium adjustment percentage for the 2021 benefit year was 1.3542376277 (\$6,759/\$4,991), which represents an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 35.4

¹³⁹ See Revenue Procedure 2019–29, 2019–32 IRB 620. <https://www.irs.gov/pub/irs-drop/rp-19-29.pdf>.

¹⁴⁰ The 2013 and 2020 per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) figures used for this calculation were published on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the "NHE Projections 2018–2027—Tables" link located in the Downloads section at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. A detailed description of the NHE projection methodology is also available on the CMS website.

percent over the period from 2013 to 2020. We sought comments on the proposed premium adjustment percentage.

After reviewing public comments, we are finalizing the premium adjustment percentage at the proposed value of 1.3542376277, based on the NHEA data available at the time of proposal, for the 2021 benefit year. The following is a summary of the public comments we received on the premium adjustment percentage.

Comment: We received a few comments regarding the timing of NHEA data updates that we use to calculate the premium adjustment percentage index (PAPI) and associated payment parameters. For the 2020 Payment Notice, these data were updated between the proposed and final rules, and in order to reflect the most recent data available, we updated the value of the premium adjustment percentage in the final 2020 Payment Notice accordingly. Some commenters expressed concern that updates to the NHEA data between the proposed and final rules could lead to unpredictability in benefit design and pricing. They recommended that even if NHEA data are updated between the proposed and final rules, we should finalize the premium adjustment percentage using the NHEA data that was available when the proposed rule was published.

Response: We understand some commenters' concern that issuers require the payment parameters associated with the NHEA data as early as possible prior to rate submissions to develop benefit designs and pricing. In light of these comments, we clarify that for the 2021 benefit year and beyond, we are finalizing payment parameters that depend on NHEA data, including the premium adjustment percentage and required contribution percentage, based on the data that are available as of the publication of the proposed rule for that benefit year, to increase the predictability of benefit design. These payment parameters include the premium adjustment percentage, the maximum annual limitation on cost sharing, the reduced maximum annual limitations on cost sharing for silver plan variations, and the required contribution percentage. We are finalizing a premium adjustment percentage for the 2021 benefit year at 1.3542376277, as proposed.

Comment: All commenters on this proposal expressed concern with the rate of increase in the PAPI and related payment parameters. Many commenters specifically opposed the use of a premium measure that includes individual market premium changes, on

the grounds that the use of that measure would lead to more rapid increases in consumer costs than the ESI-only premium measure utilized to calculate the PAPI prior to the 2020 benefit year. Commenters expressed concerns that more rapid increases in the premium adjustment percentage would lead to lower enrollment. We also received two comments suggesting caps to the PAPI such that, if we maintain the current measure, we should cap the PAPI to a maximum 3 percent annual increase or that we should revise the calculation to allow for a few years of transition between the ESI-only premium measure and premium measures that include individual market premiums.

Response: As stated earlier in this preamble, we are finalizing the proposed value of the premium adjustment percentage, using the measure of premium growth that accounts for individual market health insurance premiums, as well as employer-sponsored insurance that we finalized in the 2020 Payment Notice, based on the data available at the time of the proposal. We believe that a measure that incorporates employer-sponsored insurance as well as individual market premiums is an appropriate, comprehensive measure of premium growth as discussed in the 2020 Payment Notice.¹⁴¹ As such, we will continue to calculate the premium adjustment percentage using NHEA projections of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance).

(1) Maximum Annual Limitation on Cost Sharing for Plan Year 2021

We proposed to increase the maximum annual limitation on cost sharing for the 2021 benefit year based on the proposed value calculated for the premium adjustment percentage for the 2021 benefit year. Under § 156.130(a)(2), for the 2021 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 2021. For other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of \$50.

Using the premium adjustment percentage of 1.3542376277 for 2021 as proposed, 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, 2013,¹⁴² we proposed that the 2021 maximum annual limitation on cost sharing would be \$8,550 for self-only coverage and \$17,100 for other than self-only coverage. This represents an approximately 4.9 percent increase above the 2020 parameters of \$8,150 for self-only coverage and \$16,300 for other than self-only coverage. We solicited comment on this proposal.

After reviewing public comments, we are finalizing the maximum annual limitation on cost sharing values at \$8,550 for self-only coverage and \$17,100 for other than self-only coverage, as proposed. The following is a summary of the public comments we received on the maximum annual limitation on cost sharing.

Comment: Some commenters requested that HHS work with the IRS to align the maximum annual limitation on cost sharing we publish based on the PAPI and the maximum out-of-pocket value the IRS publishes regarding high-deductible health plans (HDHPs). These commenters are concerned that differences between the two maximum out-of-pocket values would prevent issuers from offering HDHPs that will allow individuals to contribute to health savings accounts (HSAs) as bronze plans.

Response: We recognize that the different requirements published by the IRS and by HHS may result in some issuers being unable to offer HSA-eligible HDHPs, in accordance with sections 223(c) and (g) of the Code, within the actuarial value range for bronze metal level plans. IRS and HHS are required to follow separate statutes for the maximum annual limitation on cost sharing. The calculation for the maximum annual limitation on cost sharing published by HHS is mandated by section 1302(c)(1) of the PPACA and depends on the premium adjustment percentage defined by section 1302(c)(4) of the PPACA as a measure of growth in average per capita premiums. The annual updates to the HDHP maximum out-of-pocket published by the IRS, however, are mandated by section 223(g) of the Code and depend on a cost-of-living adjustment defined as a measure of growth in the Chained Consumer Price Index for all Urban Consumers by section 1(f)(3) of the Code. HHS will continue to adhere to the calculation of the maximum annual limitation on cost sharing mandated by the PPACA.

b. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

We proposed to continue to use the method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations to serve enrollees at three ranges of household income below 250 percent of the federal poverty level (FPL). We are finalizing the reductions in the maximum annual limitation on cost sharing as proposed.

Sections 1402(a) through (c) of the PPACA direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver-level QHP. In the 2014 Payment Notice, we established standards related to the provision of these 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 PPACA, section 1402(c)(1)(B)(ii) of the PPACA states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AV of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) of the PPACA (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee).

As we proposed, the 2021 maximum annual limitation on cost sharing would be \$8,550 for self-only coverage and \$17,100 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. In the proposed rule, we described our analysis for the 2021 plan year and our proposed results.

¹⁴¹ See 84 FR 17454 at 17540.

¹⁴² See Revenue Procedure 2013–25, 2013–21 IRB 1110. <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

(1) Analysis for Determining the Reduced Maximum Annual Limitation on Cost Sharing

Consistent with our analysis in the 2014 through 2020 Payment Notices, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to the proposed estimated 2021 maximum annual limitation on cost sharing for self-only coverage (\$8,550). The test plan designs are based on data collected for 2020 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 2021, the test silver level QHPs included a PPO with typical cost-sharing structure (\$8,550 annual limitation on cost sharing, \$2,650 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing (\$6,800 annual limitation on cost sharing, \$3,000 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$8,550 annual limitation on cost sharing, \$4,375 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: \$500 inpatient stay per day, \$500 emergency department visit, \$30 primary care office visit, and \$55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the draft version of the 2021 AV

Calculator¹⁴³ and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 100 and 150 percent of FPL (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (2/3 reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively).

In contrast, the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL (1/2 reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of FPL be reduced by approximately 1/5, rather than 1/2, consistent with the approach taken for benefit years 2017 through 2019. We further proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of FPL be reduced by approximately 2/3, as specified in the statute, and as shown in Table 4.

The proposed reductions in the maximum annual limitation on cost

sharing must adequately account for unique plan designs that may not be captured by our three model QHPs. We also noted that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in the aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level.

In prior years we found, and we continue to find, that for individuals with household incomes of 250 to 400 percent of FPL, without any change in other forms of cost sharing, the statutory reductions in the maximum annual limitation on cost sharing will cause an increase in AV that exceeds the maximum 70 percent level in the statute. As a result, we did not propose to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent of FPL. We solicited comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing for 2021.

We note that for 2021, as described in § 156.135(d), states are permitted to submit for HHS approval state-specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1, 2019 deadline.

TABLE 4—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2021

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2021	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2021
Individuals eligible for CSRs under § 155.305(g)(2)(i) (100–150 percent of FPL)	\$2,850	\$5,700
Individuals eligible for CSRs under § 155.305(g)(2)(ii) (151–200 percent of FPL)	2,850	5,700
Individuals eligible for CSRs under § 155.305(g)(2)(iii) (201–250 percent of FPL)	6,800	13,600

We received no comments on the reductions in the maximum limitations on cost sharing apart from those already discussed in this preamble. As such, we are finalizing the 2021 values as proposed (reproduced in Table 4).

c. Cost-Sharing Requirements
(§ 156.130)

We proposed to revise § 156.130(h) to provide that, notwithstanding any other provision on the annual limitation on

cost sharing, and to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers to enrollees for specific prescription drugs are permitted, but not required, to be counted toward the annual limitation on cost sharing. We also proposed to interpret the definition of cost sharing to exclude expenditures covered by direct

drug manufacturer support. We are generally finalizing the policy as proposed with a minor revision to the title of the regulatory provision to reflect its application to all forms of direct support provided by drug manufacturers, which include coupons for specific prescription drugs. However, we are not finalizing the proposed interpretation of the definition of cost sharing to exclude these amounts from that term.

¹⁴³ Available at <https://www.cms.gov/ccio/resources/regulations-and-guidance/index>.

In the 2020 Payment Notice at § 156.130(h)(1), we finalized that, for plan years beginning on or after January 1, 2020, notwithstanding any other provision of § 156.130, and to the extent consistent with applicable state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing. In that rule, we expressed concern that market distortion can exist when a consumer selects a higher-cost brand name drug when an equally effective generic drug is available.

Since finalizing § 156.130(h)(1) in that rule, we received feedback indicating confusion about whether it requires plans and issuers to count the value of all forms of direct support provided by drug manufacturers, including drug manufacturers' coupons, toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available, particularly with regard to large group market and self-insured group health plans. On August 26, 2019, HHS and the Departments of Labor and the Treasury released FAQ Part 40,¹⁴⁴ acknowledging the confusion among stakeholders and the possibility that the requirement could create a conflict with certain rules for HDHPs that are intended to allow eligible individuals to establish an HSA.

Specifically, Q&A–9 of IRS Notice 2004–50¹⁴⁵ states that the provision of drug discounts will not disqualify an individual from being an eligible individual if the individual is responsible for paying the costs of any drugs (taking into account the discount) until the deductible under the HDHP is satisfied. Thus, Q&A–9 of IRS Notice 2004–50 requires an HDHP to disregard drug discounts and other manufacturer and provider discounts when determining if the deductible for an HDHP has been satisfied, and only allows amounts actually paid by the individual to be taken into account for that purpose. Therefore, an issuer or sponsor of an HDHP could be put in the position of complying with either the requirement under the 2020 Payment Notice for limits on cost sharing in the case of direct support provided by drug

manufacturers for a brand name drug with no available or medically appropriate generic equivalent or the IRS rules for minimum deductibles for HDHPs, but potentially being unable to comply with both rules simultaneously.¹⁴⁶

Accordingly, in FAQ Part 40, we explained that we intended to undertake rulemaking in the HHS Notice of Benefit and Payment Parameters for 2021, in consultation with the Departments of Labor and the Treasury to address the conflict, and that until the 2021 Payment Notice is issued and effective, the Departments will not initiate an enforcement action if an issuer of group or individual health insurance coverage or a group health plan excludes the value of direct support provided by drug manufacturers from the annual limitation on cost sharing, including in circumstances in which there is no medically appropriate generic equivalent available.

In the proposed rule, we proposed to revise § 156.130(h) in its entirety to provide that, notwithstanding any other provision of the annual limitation on cost sharing regulation, and to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers to enrollees for specific prescription drugs are permitted, but not required, to be counted toward the annual limitation on cost sharing. Under the proposal, plans and issuers would have the flexibility to determine whether to include or exclude dollar amounts of direct support provided by drug manufacturers from the annual limitation on cost sharing, regardless of whether a generic equivalent is available, when otherwise consistent with applicable requirements.

We also proposed to interpret the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons, without proposing any changes to the regulatory definition of cost sharing under § 155.20. Under the proposed interpretation, the value of the direct support provided by drug manufacturers would not be required to count towards the annual limitation on cost sharing.

Section 1302(c)(3)(A) of the PPACA defines the term cost sharing to include: (1) Deductibles, coinsurance, copayments, or similar charges; and (2)

any other expenditure required of an insured individual which is a qualified medical expense¹⁴⁷ with respect to EHB covered under the plan. Section 1302(c)(1) of the PPACA states that the cost sharing incurred under a health plan shall not exceed the annual limitation on cost sharing. We explained that, under the proposed interpretation, direct support provided by drug manufacturers, including coupon amounts, would be viewed as reducing the costs incurred by an enrollee under the health plan because they would reduce the amount that the enrollee is required to pay in order to obtain coverage for the drug. The value of the coupon would not be considered a cost incurred by or charged to the enrollee; thus, we explained its value would not be required to count toward the annual limitation on cost sharing.

Under this proposed interpretation, and to the extent consistent with applicable state law, we sought to provide issuers of non-grandfathered individual and group market coverage, and all non-grandfathered group health plans subject to section 2707(b) of the PHS Act, flexibility to determine whether to include or exclude amounts of direct support provided by drug manufacturers from the annual limitation on cost sharing, regardless of whether a medically appropriate generic equivalent is available.¹⁴⁸ The proposal would enable issuers and group health plans to continue longstanding practices with regard to how and whether direct drug manufacturer support accrues towards an enrollee's annual limitation on cost sharing.¹⁴⁹

As noted, the proposal would also afford issuers of non-grandfathered individual and group market coverage, and all non-grandfathered group health plans subject to section 2707(b) of the PHS Act, the same opportunity as under the current § 156.130(h)(1) to incentivize generic drug usage by excluding the amounts of direct drug manufacturer support for brand name drugs from the annual limitation on cost sharing when a medically appropriate generic equivalent is available. We

¹⁴⁷ As defined in section 223(d)(2) of the Code.

¹⁴⁸ We note that an issuer or group health plan that elects to credit direct drug manufacturer support amounts toward the minimum deductible of an HDHP could disqualify an individual from making HSA contributions, pursuant to Q&A–9 of Notice 2004–50.

¹⁴⁹ The annual limitation on cost sharing under section 1302(c)(1) of the PPACA is applied to non-grandfathered group health plans by section 2707(b) of the PHS Act, which is incorporated by reference into ERISA and the Code. Therefore, we generally refer to both issuers and group health plans when describing the policy regarding the annual limitation on cost sharing in this section of the preamble.

¹⁴⁴ Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf>.

¹⁴⁵ 2004–2 C.B. 196, available at <https://www.irs.gov/pub/irs-drop/n-04-50.pdf>.

¹⁴⁶ FAQs About Affordable Care Act Implementation Part 40. August 26, 2019. Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf> and <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-40>.

stated that we expect issuers and group health plans to be transparent with enrollees and prospective enrollees regarding whether the value of direct drug manufacturer support accrues to the annual limitation on cost sharing as such policies would affect enrollees' out-of-pocket liability under their plans. We also stated we would expect issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits.

We received many comments on this proposal.

Comment: Some commenters supported the proposed policy, noting that the policy would give health insurance issuers and group health plans increased flexibility to address the cost of brand name drugs and lower the cost of health insurance overall. Others supported the proposal's deference to state law, regulations, and guidance on whether drug manufacturer support accrues towards the annual limitation on cost sharing. One commenter recommended that the regulation text be revised to require that all drug manufacturer financial assistance be treated the same way, whether provided directly or through a surrogate organization.

Numerous commenters and individuals opposed permitting insurers to exclude direct support from drug manufacturers from amounts enrollees have paid toward the annual limitation on cost sharing. These commenters urged HHS not to finalize the proposal, and to leave the policy established in the 2020 Payment Notice. These commenters asserted that the proposal is in direct opposition to the administration's stated goals of reducing drug prices for patients. Additionally, they expressed concern that patient costs would increase dramatically, which could lead to greater non-adherence to medications and ultimately impact the life and health of patients.

Response: For the reasons stated in the proposed rule, and as further described in responses to comments in this subsection of the preamble, we are generally finalizing this policy as proposed, except we are making a non-substantive change to the title of the regulatory provision to "Use of direct support offered by drug manufacturers" and are not finalizing the proposed interpretation of the definition of cost sharing to exclude expenditures covered by direct drug manufacturer support.

We agree with commenters who supported the provision of the policy

that states it is only effective to the extent consistent with state law. As finalized, § 156.130(h) provides states with the flexibility to promulgate rules that would require direct drug manufacturer support amounts to be counted by health insurance issuers towards the annual limitation on cost sharing. To the extent states want to require health insurance issuers to count direct drug manufacturer support amounts towards the annual limitation on cost sharing, they can do so when such action would be consistent with other applicable laws and rules (for example, federal non-discrimination requirements). At the same time, however, states also have flexibility to promulgate rules that would mandate exclusion of such amounts from the annual limitation on cost sharing.

We appreciate commenters' concerns that the proposal could raise out-of-pocket costs for consumers who use brand name drugs. However, we believe the impact of such costs may be limited if issuers that currently allow these amounts to be counted toward enrollees' deductibles or their annual limitation on cost sharing continue their current behavior, which we believe will be the case.¹⁵⁰ As stated in the proposed rule, the flexibility provided under this policy will enable issuers and group health plans to continue longstanding practices with regard to how and whether direct drug manufacturer support accrues towards an enrollee's annual limitation on cost sharing. Prior to the 2020 Payment Notice, federal rules did not explicitly state whether issuers and group health plans had the flexibility to determine how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing. While the policy finalized in the 2020 Payment Notice may have caused confusion, FAQ Part 40, released in August 2019, provided issuers and group health plans with sufficient notice that issuers and group health plans may choose to maintain their existing plan designs for plan year 2020. This final rule, combined with FAQ Part 40, ensures that issuers and group health plans need not make changes to how they have historically handled direct drug manufacturer support amounts. Issuers and group health plans will continue to have flexibility, subject to state law and other applicable requirements (if any), to determine if and how to factor in direct drug manufacturer support amounts

¹⁵⁰ In fact, no comments submitted by the health insurance industry on this policy in the 2021 Payment Notice proposed rule expressed a desire to change their current practices.

towards the annual limitation on cost sharing. Longstanding practices of including these amounts towards the annual limitation on cost sharing can continue. Although, consistent with the Administration's efforts to combat high and rising out-of-pocket costs for prescription drugs, we continue to encourage issuers to find innovative methods to address the market distortion that occurs when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug. This includes, to the extent consistent with state law and other applicable requirements, leveraging the flexibility to exclude direct drug manufacturer support amounts from the annual limitation on cost sharing, given the market distortive effects such support can cause. We do not expect any significant increases in patient costs or non-adherence to medications if issuers choose to continue their current behavior. Therefore, we believe the impact to consumers will be minimal if issuers choose to continue their current behavior.

While we believe it is unlikely that issuers will choose to change their longstanding practices, we acknowledge the possibility that some issuers or group health plans may make changes to their plan designs to exclude direct drug manufacturer support amounts from the annual limitation on cost sharing. In these limited circumstances, consumers enrolled in such plans may see changes to their plan design, such as changes to formulary designs or cost-sharing structures, which may increase or decrease their out-of-pocket costs for a specific prescription drug. Given the multitude of variables and considerations that are out of HHS's control, we cannot project this burden with sufficient certainty. For issuers and group health plans that do make changes to their longstanding practices, we continue to encourage transparency with regard to changes in how direct drug manufacturer support amounts count towards the annual limitation on cost sharing. For example, we encourage issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits. If we find that such transparency is not provided, HHS may consider future rulemaking to require that issuers provide this information in plan documents and collateral material. We also remind issuers that when determining if and how to factor in direct drug

manufacturer support amounts towards the annual limitation on cost sharing, such policies must apply in a uniform, non-discriminatory manner.¹⁵¹ Lastly, while we did not propose and are not finalizing policies regarding indirect drug manufacturer support of specific drugs, we do intend to continue to monitor the impact of such support.

Comment: Some commenters supported the policy, stating that it ensures the viability of HSAs that may be paired with HDHPs. Opposing commenters expressed concern that HHS's rationale for choosing not to maintain and enforce the rule as finalized in the 2020 Payment Notice is based on a misinterpretation of Q&A 9 of IRS Notice 2004–50 and that no conflict exists. Several commenters questioned whether the scenario described in Q&A 9 of IRS Notice 2004–50 referenced in the proposed rule applies to direct drug manufacturer support. One commenter noted that a “discount card” is separate and distinct from a drug maker coupon, traditionally used in lieu of health insurance, and therefore, was excluded from the calculation of annual deductibles when the IRS issued Notice 2004–50. This commenter also noted that copay assistance from a drug maker has traditionally counted toward annual deductibles and out-of-pocket limits, and therefore, it is highly unlikely that the IRS was referring to drug manufacturers' coupons in its notice.

Many commenters requested that HHS clarify that the rule does not conflict with rules relating to HDHPs with HSAs. Many commenters also noted that the 2020 Payment Notice could not conflict with IRS Notice 2004–50 because it is explicitly described as “guidance on Health Savings Accounts,” and therefore, does not carry the force of law. One commenter noted that in section 223(c)(2) of the Code, which defines the term “high deductible health plan,” that there was no mention in the statute of precisely who must bear the cost of the established deductible, nor any requirement that assistance with cost sharing, from any party, be excluded from the deductible.

Another commenter was concerned that health plans could misinterpret these statements to mean that HHS is directing them to exclude manufacturer assistance from patient cost-sharing limits, which could accelerate a trend toward “accumulator adjustment programs,” which are utilization management tools pharmacy benefit

managers and health plans may use that exclude copay assistance from counting toward a patient's deductible or annual limitation on cost sharing.

Response: As explained in FAQ Part 40, since publication of the 2020 Payment Notice, the Departments received feedback indicating there was confusion about whether the HHS policy finalized in the 2020 Payment Notice required plans and issuers to count the value of drug manufacturers' coupons toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available, particularly with regard to large group market and self-insured group health plans. The Departments considered the information provided by stakeholders and agreed that the federal standards regarding the application of drug manufacturers' coupons to the annual limitation on cost sharing was ambiguous. FAQ Part 40 also explained that the Departments would not initiate an enforcement action if an issuer of group or individual health insurance coverage or a group health plan excludes the value of direct support provided by drug manufacturers from the annual limitation on cost sharing. In the proposed rule and this final rule, we seek to clarify the HHS policy and address the confusion, including the potential conflict, identified by stakeholders.

Since its enactment, section 223 of the Code has provided that individuals covered by an HDHP may not have medical expenses paid by other coverage prior to satisfying the deductible and remain eligible to contribute to an HSA (with certain limited exceptions, such as preventive care or disregarded coverage). There is no requirement that individuals covered by an HDHP exclusively pay for medical expenses they incur before meeting the deductible (and so, for example, family members may provide assistance as a gift to the individual, which may include paying for medical expenses on behalf of the individual). However, the HDHP is not permitted to credit the deductible in a manner that does not reflect the actual cost of medical care to the individual.

Whether or not this principle is directly applicable to a particular arrangement, it is consistent with the guidance provided in IRS Notice 2004–50. If a third party involved in the provision of a service or product that resulted in the medical expense, such as a drug manufacturer, has arranged for a rebate or discount for the individual tied to the individual incurring the medical expense, whether via a drug

discount card or a drug coupon, the true economic cost to the individual is the net amount incurred. Accordingly, to meet the requirements of section 223 of the Code, an HDHP may only take into account that net amount when determining whether the individual has satisfied the deductible. Therefore, a conflict between the HHS policy finalized in the 2020 Payment Notice and the provisions of section 223 of the Code and IRS guidance may exist for issuers who elect to include drug manufacturer support amounts towards the consumer's deductible and annual limitation on cost sharing if the consumer is enrolled in an HDHP coupled with an HSA. In addition, stakeholders expressed confusion about these issues and the possibility that the HHS policy on the annual limitation on cost sharing could create a conflict with certain IRS rules. For example, stakeholders raised questions related to certain administrative issues related to how to determine and apply the net amount to the deductible when an individual receives this type of payment. The Department of the Treasury and the IRS continue to review the comments from stakeholders on the IRS rules on HDHPs to determine if additional guidance would assist in lowering plan burdens while still ensuring the deductible is applied in compliance with the requirements of section 223 of the Code. In this rule, we clarify that the HHS policy on the annual limitation on cost sharing is intended to provide maximum flexibility and allow issuers to avoid this type of conflict for those situations where it may arise.

Under the policy finalized in this rule, issuers have flexibility, when consistent with state law, to determine if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing, subject to applicable requirements such as federal non-discrimination laws.

Finally, HHS further clarifies that, under the policy finalized in this rule, issuers and group health plans remain free to continue longstanding policies with regard to how direct drug manufacturer support accrues towards accumulators. We do not require and are not directing issuers and group health plans to any specific practice with regards to how these amounts are treated with respect towards accumulators. However, recognizing the market distortion effects related to direct drug manufacturer support amounts when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug and as part of our efforts

¹⁵¹ See, for example, 45 CFR 146.121, 147.104(e), 147.110, 156.125, and 156.225, as applicable.

to combat the high and rising out-of-pocket costs for prescription drugs, we encourage issuers and group health plans to consider the flexibility to exclude these amounts from the annual limitation on cost sharing as one tool that could be used to address these concerns.

Comment: Multiple commenters expressed concern about our interpretation of the term “cost sharing.” Most commenters found the interpretation of cost sharing in the proposed rule to be inconsistent with the definition of “cost sharing” in 45 CFR 155.20, which provides that “cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits.” Commenters argued that drug manufacturer coupons offered on behalf of plan enrollees fall within the definition of cost sharing. One commenter noted the proposed rule failed to acknowledge that many other forms of patient assistance exist beyond direct drug manufacturer support, such as crowdfunding amounts, durable medical equipment (DME) manufacturer support, and waived medical debt, and thus failed to explain why the proposal singles out direct drug manufacturer assistance, or to explain how the policy, more broadly applied, would impact these other types of assistance.

Response: After consideration of comments, we are not finalizing the proposed interpretation to exclude expenditures covered by drug manufacturer coupons and other drug manufacturer direct support from the definition of cost sharing at 45 CFR 155.20. Excluding such amounts from the federal definition of cost sharing would be inconsistent with the flexibility we are seeking to provide to issuers in this rulemaking and could be seen as a barrier for issuers who want to include these amounts towards a consumer’s annual limitation on cost sharing when otherwise consistent with applicable federal and state requirements.

As some commenters noted, drug manufacturer coupons offered to plan enrollees can be interpreted as falling within the existing definition of cost sharing. More specifically, “cost sharing,” as defined at section 1302(c)(3)(A) of PPACA and implemented at § 155.20, are expenditures required by or on behalf of an enrollee with respect to EHB, and include deductibles, coinsurance, copayments or similar charges. The value of the direct drug manufacturer support can be considered part of the overall charges incurred by the enrollee as the consumer cannot obtain the drug

without providing the full amount owed. For example, if a consumer is responsible for a \$50 co-pay for a brand name drug, the consumer cannot obtain the drug at the point of sale without providing the full \$50 (whether with \$50 cash, or \$30 cash with the \$20 coupon). At the same time, however, as stated in the proposed rule, the value of the direct drug manufacturer support could be viewed as not representing costs incurred by or charged to enrollees. Instead, such amounts could be viewed as representing a reduction, by drug manufacturers, in the amount that the enrollee is required to pay at the point of sale in order to obtain the drug. We have therefore determined that the term “cost sharing” is subject to interpretation regarding whether these amounts fall under this definition. To provide maximum flexibility for states and issuers to decide if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing, we are not finalizing the proposed interpretation to exclude such amounts from the definition of cost sharing.

For issuers who elect to include these amounts towards a consumer’s annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For issuers who elect to not count these amounts towards the consumer’s annual limitation on cost sharing, the value of the direct drug manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay. As we explained above, when determining if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing, issuers must apply such policies in a uniform, non-discriminatory manner. In addition, issuers should be clear and transparent in communications with enrollees and prospective enrollees regarding whether the value of drug manufacturer support accrues to the annual limitation on cost sharing. We encourage issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits.

We also disagree with comments that the proposed rule did not adequately explain the policy or the rationale for tailoring this policy to direct support provided by drug manufacturers. We explained in the proposed rule that the flexibility afforded under this policy was proposed specifically to address market distortion caused by direct

support, including coupons, from drug manufacturers. As we explained in the 2020 Payment Notice proposed rule, we recognize that copayment support may help enrollees by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients.¹⁵² However, the availability of a coupon or other direct support may cause physicians and enrollees to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices which can distort the market and the true cost of drugs. Such direct support from drug manufacturers can add significant long-term costs to the health care system. In some cases, this direct support may be increasing overall drug costs and can lead to unnecessary spending by issuers, which is passed on to all patients in the form of increased premiums and reduced coverage of other potentially useful health care interventions. Further, the Administration has identified high and rising out-of-pocket costs for prescription drugs, among other issues, as a challenge to consumers. For these reasons, we pursued a policy that was focused on direct drug manufacturer support. We currently have no evidence that the other types of support identified by the commenter (for example, crowdfunding amounts, waived medical debt, or support toward the purchase of DME) has similar distortive effects on the market as manufacturer support for brand name prescription drugs.¹⁵³ Further, we are unaware of any DME providers that provide financial incentives to compete with ‘generic’ versions of their product. Thus, we did not propose and are not finalizing cost sharing policies regarding such amounts, but will monitor them and their potential impact on the market for potential future rulemaking.

Comment: Several commenters appreciated the recommendation that issuers and group health plans consider adopting the practice of excluding any value an enrollee may obtain from a prescription drug manufacturer’s cost-sharing assistance program and should

¹⁵² See 84 FR 227 at 290–291.

¹⁵³ HHS previously identified concerns with respect to cost-sharing support from hospitals, other healthcare providers and other commercial entities. See, for example, <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/third-party-qa-11-04-2013.pdf>. We also continue to monitor these practices and their impact on the market for potential further action, if necessary.

disclose this practice on all websites, brochures, plan documents and other collateral materials. However, numerous commenters expressed concern that putting the onus on issuers and group health plans to inform the consumer about any policy to not count direct drug manufacturer support towards the annual limitation on cost sharing limit is inadequate. These commenters recommended that HHS require that issuers and group health plans clearly communicate to enrollees in their summaries of benefits and coverage and in their summary plan descriptions that direct drug manufacturer support does not count toward their deductibles or out-of-pocket maximums. One commenter opposed placing a new notice requirement on issuers and group health plans. An additional commenter noted that any efforts aimed at supporting transparency must also include a requirement that drug manufacturers fully disclose all direct payments they make on behalf of plan enrollees.

Response: We agree with commenters that it is important for issuers and group health plans to be clear and transparent with consumers regarding whether direct drug manufacturer support amounts will count towards the annual limitation on cost sharing, especially when such amounts will not be counted towards the annual limitation on cost sharing. This information may be essential for a consumer in deciding between plans. However, we did not propose such a requirement in the proposed rule and are not finalizing such a requirement in this rule. We intend to continue to monitor this issue, including how issuers disclose such information and may propose further rulemaking to impose robust disclosure requirements if we find that enrollees are not provided sufficient information on these practices. Further, while we encourage drug pricing transparency among drug manufacturers, we did not propose a requirement that drug manufacturers fully disclose all direct payments that are made on behalf of plan enrollees, and therefore this issue is outside of the scope of this rule.

5. Requirements for Timely Submission of Enrollment Reconciliation Data (§ 156.265)

In the Establishment of Exchanges and Qualified Health Plans; Exchange Standards interim final rule,¹⁵⁴ we established standards for the collection and transmission of enrollment information. At § 156.265(f), we set forth standards on the enrollment

reconciliation process, specifying that issuers must reconcile enrollment with the Exchange no less than once a month. Issuers in Exchanges using the Federal platform, that is, FFEs and SBE-FP, currently update data through ongoing processes collectively referred to as Enrollment Data Alignment, which includes 834 transactions, the monthly enrollment reconciliation cycle, and two dispute processes (enrollment disputes and payment disputes) that are used to make enrollment updates that cannot be handled through monthly reconciliation. Issuers offering plans through State Exchanges update Exchange data through processes designed by the State Exchange.

Although the regulations in § 156.265 require issuers to reconcile enrollment with the Exchange monthly, they do not specify standards for the format or quality of these data exchanges, such as the manner in which enrollment updates must be reflected in updates of previously submitted enrollment data, or the timeframe in which issuers should report data updates and data errors to the Exchange. If QHP issuers fail to make or report enrollment updates accurately and timely, the accuracy of payment, the accuracy of enrollment data that the Exchange has available to address consumer questions, and the accuracy of the data reported to consumers on their IRS Forms 1095-A, Health Insurance Marketplace Statement, after the end of the coverage year could be affected. For example, if an issuer does not regularly update its enrollment data to reflect retroactive enrollment changes throughout the year, and instead submits large volumes of changes to the Exchange well after the plan year has ended, these late changes may trigger the mailing of corrected Forms 1095-A to consumers after tax season, creating consumer burden and confusion.

To more explicitly state requirements for issuers in the Exchanges, we proposed amending § 156.265(f) to require an issuer to include in its enrollment reconciliation submission to the Exchange the most recent enrollment information that is available and that has been verified to the best of its knowledge or belief. We also proposed to amend § 156.265(g) to direct QHP issuers to update their enrollment records as directed by the Exchange, and to inform the Exchange if any such records contain errors, within 30 days. We believe these amendments will encourage more timely reconciliation and error reporting, resulting in an improved consumer experience. We stated in the proposed rule that, for SBE-FPs,

references in this section to the “Exchange” should be understood to mean HHS, as administrator of the Federal platform. We sought comments on these proposed amendments.

After reviewing public comments, we are finalizing amendments to the enrollment reconciliation data submission requirements in § 156.265 as proposed to require an issuer to include in its enrollment reconciliation submission to the Exchange the most recent enrollment information that is available. HHS looks forward to working with issuers on improving the reconciliation process to promote the exchange of timely and accurate data between QHP issuers and Exchanges.

Below, we summarize public comments received on these proposals.

Comment: Several commenters supported the proposal stating it will help improve the enrollment reconciliation process allowing both QHPs and Exchanges to have timely and accurate data.

Response: HHS agrees with these comments and is finalizing the policy as proposed.

Comment: One commenter proposed changes to § 156.265(g)(1) and (2). This commenter asked that HHS change the word “confirm” to “verify” in § 156.265(g)(1). The commenter was concerned that use of the word “confirm” could be misunderstood as referring to the Confirmation/Effectuation ASC X12 Benefit Enrollment and Maintenance (834) file. This commenter also suggested that HHS change the word “describe” in § 156.265(g)(2) to “resolve for” as “describe” does not convey that an issuer has the responsibility to make any necessary enrollment updates in issuer systems and electronically send corresponding enrollment information to update Exchange records.

Response: HHS agrees with the recommendation regarding § 156.265(g)(1) and will amend it to avoid any potential misunderstanding. HHS does not agree with the suggested change to (g)(2). The suggested “resolve for” edit implies that it is entirely within the issuer’s control. While the issuer needs to report the problem, resolving it is a joint process that involves both the issuer and the Exchange. However, to address the issuer’s concern, we are adding the language “and resolved assigned updates” to § 156.265(f) to make it clear that the issuer is responsible for resolving assigned updates in its own system during reconciliation.

Comment: One commenter asked HHS to provide additional clarification on issuer responsibilities to send updates

¹⁵⁴ See 77 FR 18309 at 18425.

to the Exchange within 30 days of an enrollment dispute. Another commenter recommended that issuers continue submitting monthly files as part of the enrollment reconciliation process, but should not be penalized for failure to report all errors or changes within 30 days.

Response: QHP issuers should make their best effort to actively monitor their enrollment data for accuracy in real time and to report all known data errors and changes to the Exchange within 30 days. If QHP issuers fail to make or report enrollment updates accurately and timely, the accuracy of payment, the accuracy of enrollment data that the Exchange has available to address consumer questions, and the accuracy of the data reported to consumers on their IRS Form 1095-As after the end of the coverage year could be affected. HHS notes that some issuers currently review enrollment and payment data for errors after the plan year has ended, leading to late payment and Form 1095-A corrections, and therefore, we are making this change to clarify that issuers have a responsibility to actively review their data on an ongoing basis and report corrections timely to HHS. HHS intends to monitor compliance with this requirement as a risk factor for targeting issuers for payment audits.

6. Promoting Value-Based Insurance Design

In this section of the proposed rule, we sought to promote a consumer-driven health care system in which consumers are empowered to select and maintain health care coverage of their choosing. We proposed to offer QHP issuers options to assist them design value-based insurance plans that would empower consumers to receive high value services at lower cost.

In the 2017, 2018, and 2019 Payment Notices, we sought comment on ways in which HHS can foster market-driven programs that can improve the management and costs of care and that provide consumers with quality, person-centered coverage. We also sought comment on how we may encourage value-based insurance design within the individual and small group markets and ways to support issuers in using cost sharing to incentivize more cost-effective consumer behavior. We solicited comments on how HHS can better encourage these types of plan designs, and whether any existing regulatory provisions or practices discourage such designs.

We also previously noted our interest in value-based insurance designs that: Focus on cost effective drug tiering structures; address overused, higher cost

health services; provide innovative network design that incentivizes enrollees to use higher quality care; and promote use of preventive care and wellness services. In response to these comment solicitations, we received many comments supporting HHS's efforts to explore ways to encourage innovations and value-based insurance design.

In the proposed rule, we stated that we are pursuing strategies that will assist in the uptake and offering of value-based insurance design by QHP issuers. Specifically, we outlined a "value-based" model QHP that contains consumer cost-sharing levels aimed at driving utilization of high value services and lowering utilization of low value services when medically appropriate.

Currently, under our rules, issuers have considerable discretion in the design of cost-sharing structures, subject to certain statutory AV requirements, non-discrimination provisions,¹⁵⁵ and other applicable laws such as the MHPAEA (section 2726 of the PHS Act). We did not propose any changes to this flexibility. We are providing additional specificity around value-based design and how issuers could opt to incorporate such design into their QHPs. Offering a value-based insurance design QHP would be voluntary and issuers are encouraged to select services and cost sharing that work best for their consumers.

Borrowing from work provided by the Center for Value-based Insurance Design at the University of Michigan¹⁵⁶ (the Center), Table 5 lists high value services and drugs that an issuer may want to consider offering with lower or zero cost sharing. Table 5 also includes a list of low value services that issuers should consider setting at higher consumer cost sharing. High value services are those that most people will benefit from and have a strong clinical evidence base demonstrating appropriate care. The high value services and drugs identified in Table 5 are supported by strong clinical effectiveness evidence. Low value services are those services in which the majority of consumers would not derive a clinical benefit. The Center considered services that have been identified by other aligned efforts, such

¹⁵⁵ We note that issuers are also subject to federal civil rights laws, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the PPACA, and conscience and religious freedom laws.

¹⁵⁶ For more information, please see information about the VBID-X project available at <http://vbidcenter.org/initiatives/vbid-x/> and resulting white paper, available at http://vbidcenter.org/wp-content/uploads/2019/07/VBID-X-Final-Report_White-Paper-7.13.19.pdf.

as the Choosing Wisely initiative, the Value-based Insurance Design Health Task Force on Low Value Care, the Oregon Public Employee's Benefits Board, SmarterCare CA, and the Washington State Health Authority.¹⁵⁷ The Center's research has shown that a silver level of coverage base plan could alter the cost sharing as we proposed in Table 5 of the proposed rule and could achieve a zero impact on plan premiums, while incentivizing the consumer to seek more appropriate care.

TABLE 5—HIGH AND LOW VALUE SERVICES AND DRUG CLASSES

High Value Services with Zero Cost Sharing
Blood pressure monitors (hypertension)
Cardiac rehabilitation
Glucometers and testing strips (diabetes)
Hemoglobin a1c testing (diabetes)
INR testing (hypercoagulability)
LDL testing (hyperlipidemia)
Peak flow meters (asthma)
Pulmonary rehabilitation
High Value Generic Drug Classes with Zero Cost Sharing
ACE inhibitors and ARBs
Anti-depressants
Antipsychotics
Anti-resorptive therapy
Antiretrovirals
Antithrombotics/anticoagulants
Beta blockers
Buprenorphine-naloxone
Glucose lowering agents
Inhaled corticosteroids
Naloxone
Rheumatoid arthritis medications
Statins
Thyroid-related
Tobacco cessation treatments
High Value Branded Drug Classes with Reduced Cost Sharing
Anti-TNF (tumor necrosis factor)
Hepatitis C direct-acting combination
Pre-exposure prophylaxis for HIV (PrEP) ¹
Specific Low Value Services Considered
Proton beam therapy for prostate cancer
Spinal fusions
Vertebroplasty and kyphoplasty
Vitamin D testing
Commonly Overused Service Categories with Increased Cost sharing
Outpatient specialist services
Outpatient labs

¹⁵⁷ Additional information on data sources considered by the Center, please see: <https://www.choosingwisely.org/>; <http://vbidhealth.com/low-value-care-task-force.php>; <https://www.oregon.gov/oha/pebb/pages/index.aspx>; <https://www.iha.org/our-work/insights/smart-care-california>; <https://www.hca.wa.gov>.

TABLE 5—HIGH AND LOW VALUE SERVICES AND DRUG CLASSES—Continued

High-cost imaging
X-rays and other diagnostic imaging
Outpatient surgical services
Non-preferred branded drugs

¹Per 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130, non-grandfathered group health plans and non-grandfathered health insurance coverage in the group or individual markets, including QHP issuers in the individual market, will be required to cover PrEP without imposing any cost-sharing requirements for plan or policy years beginning on or after June 11, 2020, in a manner consistent with the U.S Preventive Services Task Force (USPSTF) final recommendation at <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

For issuers in Exchanges using the Federal platform, HHS is not currently offering preferential display on *HealthCare.gov* for QHPs that include value-based insurance design. However, we are considering ways in which consumers could easily identify a “value-based” QHP. We solicited comments on ways in which these “value-based” QHPs could be identified to consumers on *HealthCare.gov*, how best to communicate their availability to consumers, how best to demonstrate how the cost-sharing structures affect different consumers, and how to assist consumers in selecting a value-based QHP if it is an appropriate option.

We also solicited comment on how HHS could collect information from issuers in Exchanges using the Federal platform to indicate that their QHP includes value-based insurance design. This could include collecting the information from the issuer, instructing issuers to include “value-based” in the plan name, or establishing HHS-adopted criteria that an issuer would have to meet in order to be labeled value-based.

We also solicited comment on principles that HHS could adopt to establish what constitutes a value-based plan, perhaps establishing minimum standards, as well as obstacles to implementation. We are interested in additional ways in which HHS could provide operational assistance to issuers offering value-based QHPs. We discussed that we understand that some states require the use of standardized plan designs and may not be able to certify QHPs with alternative cost-sharing structures. We solicited comment from states that believe their cost-sharing laws would not allow for this type of plan design.

Lastly, we solicited comment on other value-based insurance design activities

HHS should pursue in the future, including applicable models for stand-alone dental plans.

Comment: The majority of comments received were in support of HHS using value-based insurance design as a tool to make coverage more affordable and to encourage consumers to seek cost-effective care. Commenters supported the approach outlined in the proposed rule as it would allow QHP issuers to maintain flexibility while incrementally introducing value-based insurance design options for Exchange enrollees. Others noted that some issuers are already offering some of the proposed cost-sharing options. A few commenters questioned the proposed approach noting that using cost sharing as a tool to influence consumer behavior could potentially introduce discriminatory benefit design or unfairly disadvantage consumers with certain chronic conditions.

Commenters offered numerous suggestions to modify the options included in the proposed rule. Specifically, commenters suggested alternative value-based approaches that would not require varying consumer cost sharing, such as providing incentives to issuers or providers to support cost effective care delivery. Several commenters supported making “value-based” plans required for QHP issuers to achieve greater standardization across QHPs. Others requested that HHS defer to states to develop specific value-based plan designs as states are in the best position to determine the needs of their population. Many commenters offered specific suggestions to the services identified in Table 5, either requesting additional services be added or identifying specific services be removed, most commonly outpatient services or non-preferred branded drugs.

Response: We appreciate the support for the options outlined in the proposed rule and are finalizing the options as proposed. We note that the option to provide varying cost sharing for any of the services identified in Table 5 is at the discretion of the issuer. As we noted in the proposed rule, issuers have considerable discretion in the design of cost-sharing structures, subject to certain statutory AV requirements, non-discrimination provisions,¹⁵⁸ and other applicable laws such as the MHPAEA (section 2726 of the PHS Act). We did not propose any changes to this

¹⁵⁸ We note that issuers are also subject to federal civil rights laws, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the PPACA, and conscience and religious freedom laws.

flexibility. We believe that maintaining issuer flexibility will allow for issuers to experiment with different cost-sharing structures that best meet their enrollee’s needs. We are not requiring issuers to offer value-based plans required. We expect that value-based plans utilizing the cost sharing suggested in Table 5 would be among many different plan designs offered by QHP issuers to meet the needs of consumers and acknowledge that QHP issuers may not offer these designs exclusively. We share concerns with commenters that varying cost sharing may not meet the needs of all consumers and encourage issuers to offer QHPs that meet the needs of a heterogeneous population. For this reason, we will not be pursuing or requiring the development of a value-based standardized option.

While we believe that states have the primary role in assessing the needs of their population, we also acknowledge that some states may not have the resources or desire to develop value-based plan options. The designs offered in this preamble are offered in such a fashion as to encourage issuers to engage in value-based plan design without stifling innovation or intruding upon state activities to do the same.

Comment: Commenters offered numerous comments on consumer understanding of the concept of value-based plans and how best to potentially identify “value-based” QHPs. Most commenters were concerned that consumers may not understand the differences between value-based plans and non-value-based plans without significant investment in education, communication, and direct assistance. Because of this, some recommended that no changes be made to *HealthCare.gov* to identify value-based plans until more research and education on best practices on how to communicate the concept of value to consumers is complete. Other commenters suggested search functionalities on *HealthCare.gov* should be enhanced to facilitate the identification of value-based plans and to allow for consumers to search for value-based services at a granular level and for pre-deductible services. Other commenters suggested that *HealthCare.gov* include static educational information for consumers and include a visual designation for consumers to easily identify QHPs with value-based cost sharing. Others stated value-based plans should be offered preferential display and be easily identified by consumers. We did not receive many specific comments on how to best demonstrate how the cost-sharing structures affect different

consumers or how to assist consumers in selecting a value-based plan, if appropriate, with many commenters suggesting HHS engage with outside stakeholders or adopt recommendations produced by other entities to the extent they are available. Other consumers requested that price and quality data be displayed alongside a value-based indicator.

Response: At this time, we are evaluating options on how best to identify value-based plans on *HealthCare.gov* and currently have no specific plans to introduce an indicator for the 2021 plan year as we have yet to develop criteria or minimum standards as to what would constitute a value-based plan, as discussed further below. As we previously noted, we also will not implement preferential display at this time. We agree that consumers will need to be educated on how to evaluate differing cost-sharing structures, how those cost-sharing structures will impact different consumers, and how best to direct certain consumers to value-based plans, if appropriate. We will consider the work of external groups in this area and as well as our own consumer testing. We will consider our operational priorities in evaluating other suggested changes to *HealthCare.gov* in the future.

Comment: Commenters suggested modifying the QHP issuer application materials to collect from the issuer whether or not the QHP was “value-based,” however many were not supportive of publicly labelling plans on *HealthCare.gov* as “value-based” as “value” can be interpreted differently by different consumers. Other commenters appeared supportive of HHS exploring standards for QHP issuers to meet in order to be designated as value-based. Commenters also noted that issuer tools to design plans, such as the actuarial value calculator may need to be modified in order to accommodate value-based plans. Some states indicated that they were modifying their existing standardized plans to accommodate the cost-sharing options in Table 5. Commenters also supported exploring adoption of value-based approaches by stand-alone dental plans.

Response: At this time, we will consider options to establish criteria for identifying value-based plans in future rulemaking. We will also consider the impact of value-based insurance design on the actuarial value calculator, if necessary. We will continue to work with states that are implementing similar approaches to ensure that we share best practices and lessons learned with value-based option adoption.

Lastly, we will continue to explore opportunities for stand-alone dental plans to adopt value-based design.

After reviewing the public comments, we are finalizing the options as proposed.

7. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

Under existing § 156.270(b)(1), issuers have been required to send termination notices, including the termination effective date and reason for termination, to enrollees only for terminations due to (1) loss of eligibility for QHP coverage, (2) non-payment of premiums, and (3) rescission of coverage. For this purpose, we considered a termination of coverage of a consumer whose enrollment would violate the anti-duplication provision of section 1882 of the Social Security Act (the Act) to be a termination because the enrollee is no longer eligible for QHP coverage under § 155.430(b)(2)(i), and therefore, issuers are required to send a termination notice under § 156.270(b)(1) when the consumer’s coverage is non-renewed.¹⁵⁹

However, there are a number of scenarios where issuers were not clearly required to send termination notices, including enrollee-initiated terminations, the death of the enrollee, the enrollee changing from one QHP to another during an annual open enrollment period or special enrollment period, and terminations for dual enrollment when an enrollee has asked the Exchange to end QHP coverage when found in other coverage, such as through Medicare PDM. We proposed to amend § 156.270(b)(1) to require QHP issuers to send to enrollees a termination notice for all termination events described in § 155.430(b), regardless of who initiated the termination. We are finalizing this provision as proposed.

The original version of § 156.270 required a termination notice when an enrollee’s coverage was terminated “for any reason,”¹⁶⁰ with a 30-day advance notice requirement. This requirement was eventually replaced with the previous requirement this rule revises.

¹⁵⁹ See 3.4.8 Medicare Enrollment and Non-renewals of the 2019 Federally-facilitated Exchanges (FFE) and Federally-facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual at https://www.regtap.info/uploads/library/ENR_EnrollmentManualForFFEandFF-SHOP_v1_5CR_092519.pdf.

¹⁶⁰ Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule, March 27, 2012 (77 FR 18310).

As bases for termination in § 155.430(b)(2) were expanded, § 156.270 was not updated in parallel. Although we recommended that issuers send termination notices whenever an enrollee’s coverage is terminated, questions arose from issuers regarding when termination notices were required. Updating our regulations to require issuers to send termination notices to enrollees for all termination events, regardless of who initiated the termination, will help streamline issuer operations and reduce confusion. This change will also help promote continuity of coverage by ensuring that enrollees are aware that their coverage is ending, as well as the reason for its termination and the termination effective date, so that they can take appropriate action to enroll in new coverage, if eligible. We solicited comments on this proposal.

Comment: All commenters who weighed in on this proposal supported it. Commenters stated that this proposal would avoid member confusion and/or unnecessary QHP inquiries and promote continuity of coverage. For example, enrollees don’t currently receive written confirmation of a termination they initiated; commenters stated that it is important for the enrollee to have in writing the actual termination date for their records, in case of miscommunication with the issuers about the preferred date or to later dispute an inaccurate Form 1095–A, and to ensure they take appropriate steps to re-enroll in coverage without a gap, if eligible.

Response: We agree with commenters and believe this change will help streamline issuer operations and reduce confusion. It will also help promote continuity of coverage by ensuring that enrollees are aware that their coverage is ending, as well as the reason for their termination, and their termination effective date, so that they can take appropriate action to enroll in new coverage, if eligible.

After reviewing the public comments, we are finalizing this provision as proposed.

8. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice,¹⁶¹ we established provisions related to confirmation and dispute of payment and collection reports. These provisions were written under the assumption that issuers would generally be able to provide these confirmations or disputes automatically to HHS. However, we found that many issuers prefer to

¹⁶¹ See 78 FR 65045 at 65080.

research payment errors and use enrollment reconciliation and disputes to update their enrollment and payment data, and are unable to complete this research and provide confirmation or dispute of their payment and collection reports within 15 days, as currently required under § 156.1210. In addition, because the FFE typically reflects enrollment reconciliation updates 1 to 2 months after they have occurred, issuers attempting to comply with the 15-day deadline submit disputes that are no longer necessary after the reconciliation updates have been processed.

Therefore, we proposed to amend § 156.1210(a) to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow issuers 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.

We also proposed to remove the requirement at § 156.1210(a) that issuers actively confirm payment accuracy to HHS each month, as well as the language in § 156.1210(b) regarding late filed discrepancies. Instead, we proposed to amend § 156.1210(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. Under the proposed approach, issuers would also have an opportunity as part of the annual confirmation process to notify HHS of disputes related to identified inaccuracies. In the proposed rule, we explained that the changes are based on our experience with current enrollment and payment operations, which include frequent updates to enrollment and payment data throughout the year that we believe make monthly confirmation unnecessarily burdensome. We also explained that we believed that the late filed discrepancy process in § 156.1210(c) was unnecessary and duplicative of the payment process modifications proposed in § 156.1210 and the adjustments to the enrollment process proposed in § 156.265(f).

We also explained that HHS intends to work cooperatively with issuers that make a good faith effort to comply with these procedures. We noted that issuers could demonstrate that they are working in good faith cooperatively with HHS by sending regular and accurate enrollment

reconciliation files and timely enrollment disputes throughout the applicable enrollment calendar, submitting payment disputes within the 90-day dispute window, 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.

We sought comments on these proposed amendments to § 156.1210. After reviewing public comments, we are finalizing the amendments as proposed to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow issuers more time to research, report, and correct inaccuracies through other channels. We are also finalizing the amendments to § 156.1210(b) and (c) as proposed, to require issuers to provide an annual confirmation after the end of the payment year, in a form and manner specified by HHS and to remove the language that has become duplicative regarding discrepancies to be addressed in future reports. HHS intends to continue working with issuers on potential further improvements to the payment and collections reports process.

Comment: Several commenters supported these amendments saying they appreciate HHS's interest in removing unnecessary reporting requirements to reduce administrative burden for issuers, as well as HHS's intention to work cooperatively with issuers that make a good faith effort to comply with these requirements. These commenters also supported the proposed change from a 15 day to 90 day reporting timeframe and appreciate the additional time to report payment inaccuracies as this better accounts for monthly billing cycles. One commenter recommended that the annual certification process occur after March following the applicable benefit year to account for the 90-day window for reporting payment inaccuracies.

Response: We appreciate the comments and are finalizing the amendments to § 156.1210 as proposed. We also note that we intend to conduct the annual certification process under § 156.1210(b) after the final April enrollment reconciliation file is issued. Additional details on the form and manner for submission of this annual confirmation will be provided in future guidance.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Reporting Requirements Related to Premiums and Expenditures (§ 158.110)

We proposed to amend § 158.110(a) to clarify the requirement that expenses for functions outsourced to or services provided by other entities retained by an issuer must be reported consistently with how expenses must be reported when such functions are performed directly by the issuer. Such entities include third-party vendors, other health insurance issuers, and other entities, whether affiliated or unaffiliated with the issuer.

In the preamble to the proposed rule, we identified several technical guidance documents¹⁶² that HHS released to address specific issues and circumstances related to the reporting of third-party expenses for MLR purposes. The guidance generally specifies that the administrative cost and profit component of payments to third-party vendors may not be included in an issuer's incurred claims or QIA, except in the case of capitation payments to clinical providers or to third-party vendors for the provision of clinical services directly to enrollees through the vendors' own employees. The guidance also generally specifies that payments to third-party vendors to perform administrative functions on behalf of the issuer must be reported as a non-claims administrative expense. In order to consolidate and clarify the MLR treatment of payments to third-party vendors and other entities, we proposed to revise § 158.110(a) to capture the requirement that expenses for functions outsourced to or services provided by other entities retained by an issuer must be reported consistently with how expenses must be reported when incurred directly by the issuer. We solicited comments on this proposal.

After considering the public comments, we are finalizing the amendment to § 158.110(a) as proposed.

Comment: Several commenters supported the proposal and agreed that it would be beneficial to clarify the regulation to ensure that issuers report expenses for functions outsourced to or services provided by other entities retained by the issuers in the same manner as expenses that issuers incur

¹⁶² See May 13, 2011 CClO Technical Guidance (CClO 2011-002) Q&As #8, #11, #12 and #14, available at <https://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr-guidance-20110513.pdf>. Also see July 18, 2011 CClO Technical Guidance (CClO 2011-004) Q&A #19, available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/20110718_mlr_guidance.pdf.

directly. One commenter opposed the proposal because of concern that issuers may be required to report confidential and proprietary information that is specific to a third-party vendor. One commenter asked HHS to clarify whether this provision will encompass risk-based payments made by health plans to contracted providers. Another commenter requested that we delay the applicability date of the proposed amendment to give large group issuers additional time to renew outsourced contracts.

Response: With respect to the comment regarding disclosure of confidential and proprietary information, we note that nothing in the existing MLR regulations and guidance or the amendments to § 158.110(a) finalized in this rule requires an issuer to report confidential and proprietary information specific to a third-party vendor or other entity it retains, as the expenses for functions outsourced to or services provided by such entities are reported only in the aggregate, generally combined with the issuer's non-outsourced expenses, and allocated to the applicable state and market. With respect to the question regarding payments to risk-bearing providers, we clarify that the amendments to § 158.110(a) do not modify the February 10, 2012 CCIIO Technical Guidance (CCIIO 2012-001)¹⁶³ Q&As ##20-22. That guidance clarified that issuers may include in incurred claims payments to certain clinical (but not pricing) risk-bearing entities such as Accountable Care Organizations (ACOs), provided certain conditions are met, except that payments to such entities for administrative functions performed on behalf of the issuer may not be included in incurred claims. Finally, regarding the request to delay the applicability date for this amendment, we acknowledge the commenter's concern but note that the proposal codifies, clarifies, and aligns with the approach outlined in existing guidance. Therefore, we are not modifying the applicability date and the amendment will be applicable as of the effective date for this final rule.

2. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

We proposed to amend § 158.140(b)(1)(i) to require issuers to deduct from 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 an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer, typically a pharmacy benefit manager (PBM). In the proposed rule, we explained that the phrase "price concession," when used in this context, is 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.) regardless from whom the item of value is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, vendor, etc.).

The existing regulatory framework in § 158.140(b)(1)(i) and (b)(3)(i) through (iii) did not clearly address the situation where the administrative costs and profits related to the provision of pharmacy benefits are comprised, in whole or in part, of a portion or all of the prescription drug rebates and other price concessions that the issuer allows the entity providing pharmacy benefit management services to retain. Consequently, enrollees failed to receive the benefit of prescription drug rebates and price concessions to the extent these are retained by an entity other than the issuer and issuers faced an unlevel playing field based on the manner in which they chose to compensate entities providing pharmacy benefit management services. The existing regulations also did not clearly address situations where the issuer received a price concession related to the provision of pharmacy benefits other than a rebate.

Therefore, we proposed to revise § 158.140(b)(1)(i) to require adjustments that must be deducted from incurred claims to include 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 an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer that are associated with administering the issuer's prescription drug benefits. We explained that the proposed amendments would additionally align more closely with the MLR provisions that apply to the Medicare Advantage organizations and Part D sponsors and Medicaid managed care

organizations,¹⁶⁴ both of which require that the full amount of prescription drug rebates and price concessions be deducted from incurred claims. We further proposed that these amendments would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022). We solicited comments on all aspects of these proposals.

After considering the public comments, we are finalizing the amendment to § 158.140(b)(1)(i) as proposed to require adjustments that must be deducted from incurred claims to include 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 an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer that are associated with administering the issuer's prescription drug benefits. However, in response to comments, we are delaying the applicability date for these amendments to the 2022 MLR reporting year (MLR reports filed in 2023).

We are also updating the regulatory text to clarify that, consistent with the policy outlined in the proposed rule,¹⁶⁵ the amendment to § 158.140(b)(1)(i) requires issuers to subtract from incurred claims prescription drug rebates and other price concessions when received and retained by an issuer "and" an entity providing pharmacy benefit management services.

Comment: Most commenters supported the proposal and agreed that implementing these amendments would more accurately reflect an issuer's incurred claims that are included in the MLR rebate and calculation and align with the requirements that have been implemented in the Medicare and Medicaid MLR programs. Some commenters expressed confidence that the amendment would benefit enrollees either by lowering premiums or increasing MLR rebates, and some commenters further urged HHS to pursue robust enforcement of the

¹⁶⁴ See the Medicare Advantage program and Prescription Drug Benefit program May 23, 2013 final rule (78 FR 31284), as amended by the April 16, 2018 final rule (83 FR 16440); and the Medicaid managed care May 6, 2016 final rule (81 FR 27497) and the CMCS May 15, 2019 information bulletin available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf>.

¹⁶⁵ Namely, that the policy reflected in the amendment to § 158.140(b)(1)(i) requires issuers to deduct from incurred claims prescription drug rebates and other price concessions not only when received and retained by the issuer but also when received and retained by an entity providing pharmacy benefit management services to the issuer. See 85 FR 7088 at 7139 (February 6, 2020).

¹⁶³ Available at <https://www.cms.gov/CCIIO/Resources/Files/Downloads/2012-02-10-guidance-mlr-ipas.pdf>.

proposed requirements. A few commenters opposed the proposal, expressing concerns that it would reduce the allowable administrative costs and disadvantage PBM contracts that do not pass all prescription drug rebates and price concessions to issuers, that the amounts for prescription drug rebates and other price concessions retained by PBMs and similar entities are not readily available to issuers, and that amounts that an issuer allows the PBM to retain do not represent an issuer's expense.

Response: As explained in the proposed rule, we believe the existing regulatory framework provided an unfair advantage to issuers with PBM contracts that did not pass all prescription drug rebates and price concessions to issuers, since the regulation currently only requires issuers to deduct from incurred claims prescription drug rebates received by the issuer. This allowed such issuers to inflate incurred claims in the MLR calculation, and thus improperly increase the allowable administrative costs, relative to financially identically situated issuers who choose to compensate entities providing pharmacy management benefit services by paying a fee or inflated pharmacy reimbursement amount. Further, as discussed in the proposed rule, it is our view that allowing an entity providing pharmacy benefit management services to retain some or all of the prescription drug rebates and other price concessions that an issuer could have otherwise received is a form of compensation provided by the issuer to the entity for services that the entity performs for the issuer, and therefore is an administrative cost of the issuer. An issuer that does not outsource pharmacy benefit management services to another entity would perform such services itself, exclude such expenses from incurred claims, and report the expenses as an administrative cost. Issuers that do not outsource these services and directly negotiate prescription drug rebates for enrollees' drug utilization would also deduct from incurred claims the full amount of these rebates (as there would be no other entity retaining such amounts). Therefore, we view these amendments as a way to level the playing field among issuers, promote uniform MLR reporting, and ensure that enrollees receive the benefit of these rebates and price concessions. We also appreciate the comments urging HHS to pursue robust enforcement of the amendments and will continue to conduct enforcement activities in the MLR

oversight process, which would include review of compliance with these requirements (once effective). Lastly, we proposed that the amendment would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022) precisely in order to enable issuers to make any adjustments to their contracts with entities providing pharmacy benefit management services that may be necessary to ensure that issuers are able to obtain the information required for accurate reporting and compliance with federal MLR requirements. As detailed below, we are finalizing a later applicability date in response to comments to provide more time for issuers to update their respective contracts, as may be necessary.

Comment: A number of commenters, including both some that supported and some that opposed the proposal, requested that HHS define "price concessions" more narrowly to align with the definitions in section 1150A of the Act, as added by the PPACA, which requires PBMs to report certain prescription benefit information to HHS and that excludes certain types of fees paid to PBMs by drug manufacturers or issuers. These commenters additionally requested that HHS codify the definition of prescription drug rebates and other price concessions in the regulation and recommended that HHS do so through separate rulemaking.

Response: We appreciate these comments and will consider codifying the definition of prescription drug rebates and other price concessions through separate rulemaking in advance of the applicability date for these new reporting requirements. In addition, in light of these comments, and the delayed applicability date discussed below, we are not finalizing a definition of "price concession" in this rulemaking.

Comment: Several commenters requested that HHS delay the applicability date for these amendments until the 2022 reporting year (MLR reports filed in 2023) in order to allow additional time for issuers to negotiate contracts with entities providing pharmacy benefit management services, as well as to allow additional time for HHS to consider alternative definitions for the term "price concessions". Some commenters noted that some issuers have already executed contracts with PBMs and other entities to perform pharmacy benefit management services for 2021, such that the proposed applicability of the 2021 reporting year (MLR reports filed in 2022) may not provide sufficient time to update those contracts and allow an issuer to come

into compliance with the proposed new requirements.

Response: We acknowledge the practical considerations raised by the commenters, including with respect to the timing of contracts, and agree with commenters' recommendation to delay the applicability date of these amendments to the 2022 reporting year (MLR reports filed in 2023). This additional time will also allow us to further consider the suggested alternative definition for "price concession".

3. Activities That Improve Health Care Quality (§ 158.150)

We proposed to amend § 158.150(b)(2)(iv)(A)(5) to clarify that issuers in the individual market may include the cost of certain wellness incentives¹⁶⁶ as QIA expenses in the MLR calculation, in the same manner as is currently permitted in the group market.¹⁶⁷ The proposal reflected the fact that issuers in the individual market are currently permitted to offer participatory wellness programs, provided such programs are consistent with applicable state law and available to all similarly situated individuals,¹⁶⁸ and that some issuers in participating states may additionally offer health-contingent wellness programs under the wellness program demonstration project that HHS announced on September 30, 2019.¹⁶⁹ We proposed that this amendment would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022). We solicited comments on this proposal.

After reviewing the public comments, we are finalizing this amendment as proposed.

Comment: We received numerous comments regarding the proposed amendment to explicitly allow all issuers in the individual market to

¹⁶⁶ For this purpose, the term "wellness incentive" has the same meaning as the term "reward" in § 146.121(f)(1)(i).

¹⁶⁷ Under section 2705(j) of the PHS Act and 45 CFR 146.121(f), health-contingent and participatory wellness programs are permitted in the group market. HHS previously recognized that participatory wellness programs in the individual market do not violate section 2705 and are therefore permitted, provided that such programs are consistent with applicable state law and available to all similarly situated individuals enrolled in the individual health insurance coverage. See 78 FR at 33167. In addition, section 2705(l) of the PHS Act authorizes the Secretary to establish a 10-state wellness program demonstration project under which issuers may offer non-discriminatory wellness programs in the individual market.

¹⁶⁸ See the Incentives for Nondiscriminatory Wellness Programs in Group Health Plans; Final Rule; 78 FR 33158 at 33167 (June 3, 2013).

¹⁶⁹ <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Wellness-Program-Demonstration-Project-Bulletin.pdf>.

include certain wellness incentives as QIA in the MLR calculation. Some commenters supported the proposal because it would align the treatment of wellness programs in the group and individual markets and encourage issuers to offer wellness programs in the individual market. While the majority of commenters on this proposal expressed opposition, most of these commenters cited concerns about wellness programs themselves, such as concerns about their effectiveness and potential to discriminate, rather than concerns regarding the proposed amendment to the MLR rules.

Response: We appreciate commenters' general concerns about wellness programs, but note that we did not propose and are not making any changes to the rules regarding wellness programs.¹⁷⁰ Instead, the amendment to § 158.150(b)(2)(iv)(A)(5) is specific to the treatment of expenses of certain wellness activities for MLR reporting purposes.

We believe this amendment is appropriate and necessary as it ensures that the MLR rules are interpreted consistently across the individual and group markets, and therefore, would increase consumer choice and access to participatory wellness programs that are currently allowed in the individual market and any health-contingent wellness programs that may be available in a state that is approved to participate in the wellness program demonstration project.

4. Other Non-Claims Costs (§ 158.160)

In the proposed rule, we proposed to amend § 158.160(b)(2), to conform with the proposed amendments to § 158.140(b)(1)(i), by requiring issuers to report the prescription drug rebates received by the issuer, as well as any price concessions received and retained by the issuer, and any prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer

that are associated with administering the issuer's prescription drug benefits, as non-claims costs.

After reviewing the public comments, we are finalizing this requirement as proposed, except that the requirement will not apply to the prescription drug rebates and other price concessions received by the issuer. We are also delaying the applicability date of this amendment to the 2022 reporting year (MLR reports filed in 2023) to align with the applicability date of the amendments to § 158.140(b)(1)(i).

Comment: Several commenters pointed out that the proposal inadvertently required issuers to report prescription drug rebates and other price concessions as an administrative cost regardless of whether they are received and retained by the issuer or by the entity providing pharmacy benefit management services. The commenters noted that to the extent such amounts are received and retained by the issuer, they do not represent an administrative fee paid by the issuer to the entity providing pharmacy benefit management services, and that adding these amounts to non-claims cost may cause them to be double-counted in the administrative costs reported by the issuer.

Response: We agree with the commenters that reporting the prescription drug rebates and other price concessions received and retained by the issuer as non-claims costs may result in double-counting in MLR reports, since issuers would already report these amounts in non-claims costs to the extent the funds are used for administrative expenses. Therefore, we are finalizing this requirement as proposed, except that the requirement will not apply to the prescription drug rebates and other price concessions received by the issuer and will have a delayed applicability date, as detailed above.

IV. Collection of Information Requirements

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 8. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.¹⁷¹ Table 65 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 6—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation Title	Occupational code	Mean hourly wage (\$/hr.)	Fringe benefits and overhead (\$/hr.)	Adjusted hourly wage (\$/hr.)
Chief Executive*	11-1011	\$96.22	\$96.22	\$192.44
General and Operations Manager	11-1021	59.56	59.56	119.12
Compensation and Benefits Manager	11-3111	63.87	63.87	127.74
Lawyer	23-1011	69.34	69.34	138.68

¹⁷⁰ See 45 CFR 147.121 and 147.110.

¹⁷¹ See May 2018 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates.

Available at https://www.bls.gov/oes/current/oes_stru.htm.

TABLE 6—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES—Continued

Occupation Title	Occupational code	Mean hourly wage (\$/hr.)	Fringe benefits and overhead (\$/hr.)	Adjusted hourly wage (\$/hr.)
Legal Support Worker	23–2099	34.34	34.34	68.68

* Chief executive wage is used to estimate the state official wages.

B. ICRs Regarding Notice Requirement for Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors (§ 146.145(b)(3)(viii)(E))

In § 146.145(b)(3)(viii)(E), we require that an excepted benefit HRA offered by a non-Federal governmental plan sponsor must provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the plan, and a description or summary of the benefits. This notice must be provided on an annual basis no later than 90 days after the first day of the excepted benefit HRA plan year (or, if a participant is not eligible to participate at the beginning of the plan year, no later than 90 days after the employee becomes a participant in the excepted benefit HRA).

We estimate that for each excepted benefit HRA sponsored by a non-Federal governmental plan, a compensation and benefits manager will need 1 hour (at \$127.74 per hour) and a lawyer will need 0.5 hours (at \$138.68 per hour) to prepare the notice. The total burden for an HRA plan sponsor will be 1.5 hours with an equivalent cost of approximately \$197. This burden will be incurred the first time the non-

Federal governmental plan sponsor provides an excepted benefit HRA.

In subsequent years, if there are changes in benefits, we estimate that a compensation and benefits manager will need 0.5 hours (at \$127.74 per hour) and a lawyer will need 0.25 hours (at \$138.68 per hour) to update the notice. The total burden for an HRA plan sponsor will be 0.75 hours with an equivalent cost of approximately \$99. If there are no changes in benefits, the burden to update the notice in subsequent years is expected to be minimal and therefore is not estimated.

We estimate that approximately 901 state and local government entities will offer excepted benefit HRAs each year.¹⁷² The total burden to prepare the notices will be approximately 1,352 hours with an equivalent cost of approximately \$177,569. We estimate that approximately 10 percent of state and local government entities will make substantive changes to benefits each year and the total annual burden to update the notices will be approximately 68 hours with an equivalent cost of approximately \$8,879.

Non-Federal governmental sponsors of excepted benefit HRAs must provide the notice to eligible participants every

year. We estimate that sponsors will provide printed copies of these notices to approximately 193,715 eligible participants annually.¹⁷³ We anticipate that the notices will be approximately 1-page long, and the cost of materials and printing will be \$0.05 per notice. It is assumed that these notices will be provided along with other benefits information with no additional mailing cost. We assume that approximately 54 percent of notices will be provided electronically and approximately 46 percent will be provided in print along with other benefits information.

Therefore, state and local government entities providing excepted benefit HRAs to their employees will print approximately 89,109 notices at a cost of approximately \$4,455 annually.

The total burden to prepare and send the notices in the first year will be approximately \$182,000. In subsequent years, these employers will incur a cost of \$8,879 to update the notices and printing and materials costs of approximately \$4,455 annually. The average annual burden over 3 years will be 496 hours with an equivalent annual cost of \$65,109, and an average annual total cost of \$69,565.

TABLE 7—ANNUAL BURDEN AND COSTS

Year	Estimated number of non-federal governmental employers offering HRAs	Estimated number of notices to all eligible participants	Total annual burden (hours)	Total estimated labor cost	Total estimated printing and materials cost
2020	901	193,715	1,352	\$177,569	\$4,455
2021	901	193,715	68	8,879	4,455
2022	901	193,715	68	8,879	4,455
3 year Average	901	193,715	496	65,109	4,455

We did not receive any comments on the burden estimates. A summary of comments and response on whether the notice should be provided annually is included previously in the preamble.

C. ICRs Regarding Special Enrollment Periods (§ 155.420)

We are amending § 155.420(d)(1)(ii) to codify that qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year will be eligible for the special

enrollment period available to qualified individuals and dependents who are enrolled in any non-calendar year group health plan or individual health insurance coverage. This special enrollment period is subject to pre-enrollment eligibility verification for individuals who are newly enrolling in

¹⁷² HHS assumes that only 1 percent of state and local government entities will offer excepted benefit HRAs.

¹⁷³ HHS assumes that excepted benefit HRAs will be offered to all employees of state and local government entities that offer excepted benefit HRAs. This is an upper bound and actual number

of eligible participants is likely to be lower if excepted benefit HRAs are offered to only some employee classes.

coverage through the Exchange, and to plan category limitations for Exchange enrollees who use the special enrollment period to change to a different QHP. While the FFEs make every effort to verify an individual's special enrollment period eligibility through automated electronic means, including when it is verifying eligibility on behalf of SBE-FPs, the FFEs currently cannot electronically verify whether an individual has a non-calendar year plan year QSEHRA. Therefore, qualifying individuals will be required to provide supporting documentation within 30 days of plan selection to confirm their special enrollment period triggering event, which is the end date of their QSEHRA. Acceptable documents may include a dated letter from their employer stating when their QSEHRA plan year ends or a copy of the notice that their employer provided them with to comply with section 9831(d)(4) of the Code.¹⁷⁴

We estimate that this policy will result in relatively few additional consumers being required to submit documents to verify their eligibility to enroll through the proposed special enrollment period on Exchange, because this group consists of a subset of consumers with a QSEHRA whose QSEHRA renews on a non-calendar year plan year basis. Within that group, only those who are not already enrolled in individual market health insurance coverage in order to meet their QSEHRA's requirement to have MEC and who wish to change plans mid-calendar year will be required to submit documents to confirm special enrollment period eligibility. Additionally, because changing plans mid-calendar year will generally result in these consumers' deductibles and other cost-sharing accumulators resetting we anticipate that few consumers will opt to do so, and that there will only be a minimal increase in burden.

We solicited comment on whether or not this is the case; we received broad support for the proposal, and did not receive any comments that disagreed with or suggested that we should revise our estimate in the proposed rule that relatively few additional consumers would be required to submit documents to verify their eligibility to enroll through the proposed special enrollment period on Exchange.

¹⁷⁴ Per IRS Notice 2017-67, this notice must include the date on which the QSEHRA is first provided to the eligible employee. Therefore, it is likely that in some cases it will also include or imply the QSEHRA end date.

D. ICRs Regarding Quality Rating Information Display Standards for Exchanges (§§ 155.1400 and 155.1405)

At §§ 155.1400 and 155.1405, we codify the flexibility for State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information for their QHPs. The burden related to the proposed requirements was previously approved under OMB control number 0938-1312 (Establishment of an Exchange by a State and Qualified Health Plans PRA (CMS-10593)); the approval expired in August 2019; however, we are in the process of reinstating this information collection. The associated 60-day **Federal Register** notice published on February 25, 2020 (85 FR 10701). We do not anticipate that the flexibility we are codifying for State Exchanges that operate their own eligibility and enrollment platforms regarding the display of quality rating information for their QHPs would increase burden, as State Exchanges have the choice to pursue (or not pursue) this flexibility.

E. ICRs Regarding State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We are finalizing as proposed § 156.111(f) that specifies the type of information states are required to submit to HHS by the annual submission deadline in a form and manner specified by HHS. For a reporting package to be complete, states will need to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6). If a state does not submit an annual reporting package by the annual submission deadline, HHS will identify which benefits are in addition to EHB for the applicable plan year in the state. We are also finalizing the proposed reporting schedule, such that states will be required to notify HHS for the first year of reporting by July 1, 2021, of any benefits in addition to EHB that QHPs 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).

HHS will provide the template(s) to states that states are required to use for reporting the required information proposed in § 156.111(f)(1) through (6). Those templates, including the certification form, are available for review as part of the information collection we are amending under OMB control number: 0938-1174 (Essential Health Benefits Benchmark Plans (CMS-10448)), publishing alongside

this final rule. We intend to post state submission of these documents on the EHB website prior to the end of the plan year during which the reporting takes place. If the state does not notify HHS of its state-required benefits that are in addition to EHB in accordance with the requirements at § 156.111(f), HHS will complete a similar document for the state and post it to the CMS website.

As we did not receive any comments that specifically contested the estimated state burden associated with the annual reporting requirement and no comments regarding the estimated number of states that we anticipate will annually report to HHS versus the number we anticipate will opt to have HHS identify which benefits are in addition to EHB for the applicable plan year in the state, we are finalizing these estimates below.

We continue to anticipate that the majority of states will choose to annually report to HHS under this policy, as states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of QHP coverage of those benefits. Because we believe the information we are requiring that states report to HHS as part of this annual reporting should already be readily accessible to states, we estimate that approximately ten states will not report and the remaining states will annually report to HHS by the annual reporting submission deadline. Therefore, we estimate that approximately forty-one (41) states will respond to the information collection requirements associated with the finalized annual reporting policy.

For the first year in which the annual reporting will take place, states will be required to include a comprehensive list of all state-required benefits applicable to QHPs in the individual and/or small group markets under state mandates 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 those state mandates that were imposed after December 31, 2011, regardless of whether the state believes such state-required benefits require defrayal in accordance with § 155.170. Each annual reporting cycle thereafter, the state will only need to update the content in its report to add any new state benefit requirements, and to indicate whether state benefit requirements previously reported to HHS have been amended or repealed. Information in states' initial reports must be accurate as of a day that is at least 60 days prior to the first reporting submission deadline set by HHS. As such, we estimate that the burden estimates for states in the first

year of annual reporting will be higher than in each subsequent year.

Although we estimate a higher burden in the first year of annual reporting of state-required benefits, states are already expected to identify which state-required benefits are in addition to EHB and to defray the cost of QHP coverage of those benefits in accordance with § 155.170. Because we believe the information we are requiring states report to HHS should be readily accessible to states, we estimate that it will require a legal support worker 25 hours (at a rate of \$68.68) to pull and review all mandates, transfer this information into the HHS provided template, and validate the information in the first year of annual reporting. We estimate that it will require a general and operations manager 3 hours (at a rate of \$119.12) to then review the completed template and submit it to HHS in the first year of annual reporting. We estimate that it will require a state official 2 hours (at a rate of \$192.44) in the first year of annual reporting to review and sign the required document(s) for submission on behalf of the state, to confirm the accuracy of the submission. The information will be submitted to HHS electronically at minimal cost. Therefore, we estimate that the burden for each state to meet this reporting requirement in the first year will be 30 hours, with an equivalent cost of approximately \$2,459, with a total first year burden for all 41 states of 1,230 hours and an associated total first year cost of approximately \$100,829.

Because the first year of annual reporting is intended to set the baseline list of state-required benefits which states will update as necessary in future annual reporting cycles, we believe the burden associated with each annual reporting thereafter will be lower than the first year. We estimate that for each annual reporting cycle after the first year it will require a legal support worker 10 hours (at a rate of \$68.68) to

transfer the information about state-required benefits into the HHS provided template and validate the information. We estimate that it will require a general and operations manager 2 hours (at a rate of \$119.12) to review the completed template and submit it to HHS each year after the first annual reporting. We estimate that it will require a state official 1 hour (at a rate of \$192.44) to review and sign the required document(s) for submission on behalf of the state, to confirm the accuracy of the submission. Therefore, we estimate that the burden for each state to meet the annual reporting requirement each year after the first year of annual reporting will be 13 hours with an equivalent cost of approximately \$1,117, with a total annual burden for all 41 states of 533 hours and an associated total annual cost of approximately \$45,817. The average annual burden over 3 years will be approximately 765 hours with an equivalent average annual cost of approximately \$64,154.

We are amending the information collection currently approved under OMB control number: 0938-1174 (Essential Health Benefits Benchmark Plans (CMS-10448)) to include this burden.

F. ICRs Regarding Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

The collection of information titled, “Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers” (OMB control number 0938-1341 (CMS-10592)) already accounts for burden estimates for QHP issuers to provide notice to an enrollee if the enrollee’s coverage in a QHP is terminated. Consequently, we are not making any changes under the aforementioned control number. Since we are not making any changes to the submission process or burden, we are not making any changes under the aforementioned control number.

G. ICRs Regarding Medical Loss Ratio (§§ 158.110, 158.140, 158.150, and 158.160)

We are finalizing our proposal to amend § 158.110(a) to clarify that issuers must report for MLR purposes expenses for functions they outsource to or services provided by other entities, consistent with how issuers must report directly incurred expenses. We are also finalizing our proposal to amend § 158.140(b)(1)(i) to require issuers to deduct from incurred claims not only the 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 an entity that provides pharmacy benefit management services to the issuer (including drug price negotiation services) that are associated with administering the issuer’s prescription drug benefits. We are further amending § 158.160(b)(2) to require that the prescription drug rebates and other price concessions received and retained by an entity that provides pharmacy benefit management services to the issuer must be reported as a non-claims cost. Finally, we are finalizing our proposal to amend § 158.150(b)(2)(iv)(A)(5) to explicitly allow issuers in the individual market to include the cost of certain wellness incentives as QIA in the MLR calculation. We do not anticipate that implementing any of these provisions will require significant changes to the MLR annual reporting form or significantly change the associated burden. The burden related to this information collection is currently approved under OMB control number 0938-1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS-10418)).

H. Summary of Annual Burden Estimates for Requirements

TABLE 8—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 (\$)
§ 146.145(b)(3)(viii)(E)	0938–1361	901	193,715	0.003	496	65,109	69,565
§ 156.111	0938–1174	41	41	18.7	765	64,154	64,154
Total	942	193,756	1,261	129,263	133,719

Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 8.

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes standards related to the risk adjustment program for the 2021 benefit year, clarifications and improvements to the RADV program, as well as certain modifications that will promote transparency, innovation in the private sector, reduce burden on stakeholders, and improve program integrity. This rule finalizes additional standards related to eligibility redetermination, special enrollment periods, state selection of EHB-benchmark plan and annual reporting of state-required benefits, premium adjustment percentage, termination of coverage, excepted benefit HRAs, the MLR program, and FFE and SBE–FP user fees.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically

significant effects (\$100 million or more in any 1 year).

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. A RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of \$100 million or more in at least 1 year, and therefore, is expected to be economically significant 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 the Office of Management and Budget.

The provisions in this final rule aim to ensure taxpayer money is more appropriately spent and that states have flexibility and control over their insurance markets. They will reduce regulatory burden, reduce administrative costs for issuers and states, and may lower net premiums for consumers. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage. Although there is still some

uncertainty regarding the net effect on premiums, we anticipate that the provisions of this final rule will help further HHS’s goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices, that the insurance market offers choices, and that states have more control and flexibility over the operation and establishment of Exchanges.

Affected entities, such as states, will incur costs related to the EHB reporting requirement, defrayal of the cost of state-required benefits; implementation of new special enrollment period requirements; and non-Federal governmental plan sponsors offering excepted benefit HRAs will incur expenses associated with providing a notice. Issuers will experience a net increase in rebates paid to consumers due to the amendments to the MLR requirements. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular No. A–4, Table 9 depicts an accounting statement summarizing HHS’s assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this final rule. The effects in Table 9 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers. The annual monetized transfers described in Table 9 include an increase in risk adjustment user fee transfers and the potential net increase in rebates from

issuers to consumers due to the amendments to MLR requirements.

We are finalizing the risk adjustment user fee of \$0.25 PMPM for the 2021 benefit year to operate the risk

adjustment program on behalf of states,¹⁷⁵ which we estimate to cost approximately \$60 million in benefit year 2021, an increase of \$10 million from that estimated for the 2020 benefit

year. We are also finalizing the FFE user fee rate at 3.0 percent of premiums and the SBE–FP user fee rate at 2.5 percent of premiums, which are the same as the user fee rates for the 2020 benefit year.

TABLE 9—ACCOUNTING TABLE

Benefits:

Qualitative:

- Greater market stability resulting from updates to the risk adjustment methodology.
- Increase in consumers’ understanding of their excepted benefit HRA offer.
- Strengthened program integrity related to provisions to terminate QHP coverage for Exchange enrollees who have become deceased during a plan year and via processing voluntary terminations on behalf of Medicare, Medicaid/CHIP, if applicable, BHP, dual enrollees via PDM.
- More plan options for Exchange enrollees newly ineligible for CSRs, resulting in increased continuous coverage and associated benefit to risk pools.
- Streamlined Exchange operations by eliminating certain prospective coverage effective date rules and retroactive payment rules for special enrollment periods.

Costs	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$/year)	– \$54.57	2019	7	2020–2024
	– 51.51	2019	3	2020–2024

Quantitative:

- Costs incurred by sponsors of non-Federal governmental plans and states to comply with provisions related to notice requirement for excepted benefit HRAs and reporting related to state mandated benefits, as detailed in the Collection of Information Requirements section, estimated to be approximately \$182,000 in 2020, approximately \$105,200 in 2021 and approximately \$59,000 from 2022 onwards.
- Reduction in potential costs to Exchanges since they will 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 one-time savings of \$48.5 million in 2020 and annual savings of \$99 million in 2020 and 2021.
- Regulatory familiarization costs of approximately \$169,500 in 2020.

Qualitative:

- Increased costs due to increases in providing medical services (if health insurance enrollment increases).
- Potentially minor costs to Exchanges and DE partners to update the application and logic to account for new plan options for Exchange enrollees newly ineligible for CSRs and enrollees covered by a non-calendar plan year QSEHRA.
- Potential reduction in costs to issuers due to elimination of duplicative coverage as part of PDM.
- Potential reduction in costs to consumers due to PDM noticing efforts to notify enrollees of duplicative coverage and risk for tax liability.
- Potential costs to the Exchanges and consumers to comply with the new special enrollment period requirements.
- Potential reduction in burden for Exchanges and issuers to comply with the special enrollment period prospective coverage effective dates.

Transfers	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized (\$/year)	\$7.7	2019	7	2020–2024
	7.9	2019	3	2020–2024
Other Annualized Monetized (\$/year)	10.2	2019	7	2020–2024
	10.6	2019	3	2020–2024

Quantitative:

- Federal Transfers: Increase in risk adjustment user fee transfers from issuers to the federal government by \$10 million starting in 2021, compared to that estimated for the prior benefit year.

¹⁷⁵ As noted earlier in this final rule, no state has elected to operate the risk adjustment program for

the 2021 benefit year; therefore, HHS will operate

the program for all 50 states and the District of Columbia.

Transfers	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
<ul style="list-style-type: none"> Other Transfers: Net increase in transfers from health insurance issuers to consumers in the form of rebates of \$18.2 million per year starting in 2022 MLR reporting year, due to amendments to the MLR requirements. 				
Qualitative: <ul style="list-style-type: none"> Potential decreases in premiums and PTCs associated with adjustments to MLR. Potential decrease in APTC and CSR payments due to reduction in duplicative coverage and retroactive termination of coverage to the date of death as part of PDM and more accurate defrayal of costs for state mandated benefits. Transfer of costs from issuers to states to the extent that a state will newly defray the cost of state-required benefits it should have already been defraying. 				

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office’s (CBO) analysis of the PPACA’s impact on Federal spending, revenue collection, and insurance enrollment. The PPACA 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 9 or 10. Table 10 summarizes the

effects of the risk adjustment program on the Federal budget from FYs 2020 through 2024, 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 10.

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 2020 Payment Notice for the impacts associated with the APTCs, the premium stabilization programs, and FFE and SBE–FP user fee requirements.

TABLE 10—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FISCAL YEAR 2020–2024, IN BILLIONS OF DOLLARS ¹

Year	2020	2021	2022	2023	2024	2020–2024
Risk Adjustment and Reinsurance Program Payments	5	6	6	6	7	30
Risk Adjustment and Reinsurance Program Collections	5	6	6	6	7	30

¹ Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities. 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: Table From CBO’s March 2020 Baseline*. March 6, 2020. Available at <https://www.cbo.gov/about/products/baseline-projections-selected-programs#6>.

1. Notice Requirement for Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors (§ 146.145(b)(3)(viii)(E))

In § 146.145(b)(3)(viii)(E), we require that an excepted benefit HRA offered by a non-Federal governmental plan sponsor must provide, on an annual basis, a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the plan, and a description or summary of the benefits. This notice will provide employees with clear information regarding excepted benefit HRAs offered by their employers. Excepted benefit HRAs sponsored by non-Federal governmental entities will incur costs to provide the notice as detailed previously in the Collection of Information Requirements section.

2. Early Retiree Reinsurance Program (Part 149)

The provision to remove the regulations at part 149 of title 45 governing the ERRP will not have any direct regulatory impact since the ERRP sunset as of January 1, 2014. However, removing the regulations will reduce the volume of Federal regulations.

3. Risk Adjustment

The risk adjustment program is a permanent program created by section 1343 of the PPACA that collects charges from issuers with lower-than-average risk populations and uses those funds to make payments to issuers with higher-than-average risk populations in the individual, small group, and merged markets (as applicable), inside and outside the Exchanges. We established standards for the administration of the

risk adjustment program in subparts A, B, D, G, and H of 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 2021 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 2021 benefit year, we have 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 2021 benefit year are expected to increase from the prior 2020 benefit year estimates of approximately \$50 million to approximately \$60 million. We estimate that the total cost for HHS to

operate the risk adjustment program on behalf of states and the District of Columbia for 2021 will be approximately \$60 million, and the risk adjustment user fee will be \$0.25 PMPM. Because of the increase in costs estimated for the 2021 benefit year, we expect the final risk adjustment user fee for the 2021 benefit year to increase transfers from issuers of risk adjustment covered plans to the Federal Government by \$10 million.

Additionally, to use risk adjustment factors that reflect more recent treatment patterns and costs, we will recalibrate the HHS risk adjustment models for the 2021 benefit year by using more recent claims data to develop updated risk factors, as part of our continued assessment of modifications to the HHS-operated risk adjustment program for the individual and small group (and merged) markets. We will discontinue our reliance on MarketScan® data to recalibrate the risk adjustment models, and adopt an approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk adjustment models for the 2021 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 2020 benefit year to the 2021 benefit year due to differences in the datasets' underlying populations. We will also incorporate the proposed HCC changes beginning with the 2021 benefit year risk adjustment models to transition from the ICD-9 to ICD-10 codes. We do not expect these changes to affect the absolute value of risk adjustment transfers, or impact issuer burden beyond what we previously estimated in the 2020 Payment Notice.

4. Risk Adjustment Data Validation (§§ 153.350 and 153.630)

We are making changes to the RADV methodology for identifying outliers, which results in adjustments to transfers under § 153.350. Beginning with the 2019 benefit year of RADV, we will consider issuers to be outliers only if they have 30 or more HCCs recorded on EDGE for any HCC group in which their failure rate appears anomalous. As only a very small number of issuers will be affected by this change, and those affected already have small total plan liability risk scores for the affected HCC groups due to their low HCC counts, we expect the total reduction of burden to issuers to be small. Projections based on 2017 benefit year RADV adjustments estimate an overall 0.7 percent reduction in absolute RADV transfer

adjustments across all issuers for benefit years to which this change may apply.

We are also finalizing that the 2019 benefit year RADV will serve as a second pilot year for the purposes of prescription drug data validation in addition to the 2018 benefit year RADV. This second pilot year will provide HHS and issuers with 2 full years of experience with the data validation process for prescription drugs before adjusting transfers. We do not expect this to affect the magnitude of RADV adjustments to risk adjustment transfers, or to impact issuer burden or administrative costs beyond what we previously estimated in the 2020 Payment Notice.

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

We are finalizing the policy that HHS will not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), when the Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), for plan years 2020 and 2021. In the 2019 Payment Notice final rule, we discussed the burden associated with sampling based in part on the alternative process used for the Exchanges. HHS incurred approximately \$750,000 in costs to design and operationalize a study in 2016 and the study indicated that \$353,581 of APTC was potentially incorrectly granted to individuals who inaccurately attested to their enrollment in or eligibility for a qualifying eligible employer-sponsored plan. We placed calls to employers to verify 15,125 cases but were only able to verify 1,948 cases. A large number of employers either could not be reached or were unable to verify a consumer's information, resulting in a verification rate of approximately 13 percent. The sample-size involved in the 2016 study did not represent a statistically significant sample of the target population and did not fulfill all regulatory requirements for sampling under paragraph (d)(4)(i) of § 155.320.

We estimate that the overall one-time cost of implementing sampling would have been approximately \$8 million for the Exchanges using the Federal platform, and between \$2 million and \$7 million for other Exchanges, depending on their enrollment volume and existing infrastructure. Therefore, we estimate that the average per-Exchange cost of implementing sampling that resembles the approach taken by the Exchanges using the Federal platform would have been

approximately \$4.5 million for State Exchanges that operate their own eligibility and enrollment platform, for a total cost of \$58.5 million for the 13 State Exchanges that operate their own eligibility and enrollment platform (operating in 12 States and the District of Columbia). However, we are aware that 4 State Exchanges that operate their own eligibility and enrollment platform have already incurred costs to implement sampling and estimate that they have incurred one-time costs of approximately \$4.5 million per Exchange with a total of \$18 million and will only experience savings related to recurring costs. Therefore, the one-time savings for Exchanges using the Federal platform and the remaining State Exchanges that operate their own eligibility and enrollment platform will be approximately \$48.5 million.

We estimate the annual costs to conduct sampling on a statistically significant sample size of approximately 1 million cases to be approximately \$8 million for the Exchanges using the Federal platform and \$7 million on average for each State Exchange that operates its own eligibility and enrollment platform. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. The total annual cost to conduct sampling would have been \$91 million for 13 State Exchanges. Therefore, the total annual cost for the Exchanges using the Federal platform and the 13 State Exchanges that operate their own eligibility and enrollment platform would have been \$99 million. We estimated that relieving Exchanges of the requirement to conduct sampling for plan years 2020 and 2021 will result in annual savings of approximately \$99 million. We solicited comment on this estimate.

We received no public comments on these proposed cost savings, and therefore, we are finalizing as proposed.

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

We are amending § 155.330(e)(2)(i)(D) to clarify that the Exchanges will not redetermine eligibility for APTC/CSRs for Medicare, Medicaid/CHIP, and, if applicable, BHP for dual enrollees who provide written consent for Exchanges to end their QHP coverage prior to terminating the coverage. We anticipate that this will benefit dual enrollees, as processing a voluntary termination mitigates the risk for future tax liability for APTC/CSRs paid inappropriately during months of overlapping coverage. It will also streamline the termination

process. Additionally, we believe this provision will safeguard consumers against being enrolled in unnecessary or duplicative coverage. This provision may reduce burden on Exchanges by allowing them to streamline their PDM operations since eligibility redeterminations for APTC/CSRs are not necessary when processing a voluntary termination of coverage for a dual enrollee who has permitted the Exchange to do so, and will provide Exchanges with more flexibility in their operations.

We solicited comment on the impacts of the proposal. We received no public comments on costs or anticipated burden on states with regard to the proposed changes. Therefore, we are finalizing as proposed.

We further amend § 155.330(e)(2)(i)(D) by adding new language that clarifies when the Exchange identifies deceased enrollees via PDM, the Exchange will follow the process outlined in § 155.430(d)(7) and terminate coverage retroactively to the date of death, without the need to redetermine the eligibility of the deceased enrollee. We believe this change will reduce the amount of time a deceased enrollee remains in QHP coverage while receiving APTC/CSRs. Additionally, we believe this provision will not increase burden on State Exchanges that operate their own eligibility and enrollment platform because we believe these changes merely clarify the operational process when conducting checks for deceased enrollees and would not impose new requirements on State Exchanges that operate their own eligibility and enrollment platform. Additionally, this provision may help streamline Exchanges' PDM operations, as eligibility redeterminations are not necessary when termination of coverage is for a deceased enrollee, and will provide Exchanges with more flexibility in their operations.

We solicited comment on the impacts of the proposal. We received no public comments on costs or anticipated burden on states with regard to the proposed changes. Therefore, we are finalizing as proposed.

7. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for CSRs

We are amending § 155.420(a)(4) to allow enrollees who qualify for a special enrollment period due to becoming newly ineligible for CSRs to change to a QHP one metal level higher or lower, but delaying to January 2022 the

effective date for this modification to allow Exchanges more time to implement the change. We anticipate that this will benefit applicable enrollees and dependents by providing them with additional flexibility to change to a plan better suited to their needs based on changes to their premiums and/or cost-sharing requirements. In some cases, this change may help enrollees to maintain continuous coverage for themselves and for their dependents when they otherwise would have no longer been able to afford higher premiums or increased cost-sharing requirements of their current silver-level plan. This provision may also provide some benefit to the individual market risk pool by making it easier for those affected to maintain continuous coverage in spite of potentially significant changes in their out-of-pocket health care costs. Regardless, we believe that this change will not have a negative impact on the individual market risk pool, because most applicable enrollees will seek to change coverage based on financial rather than health needs. However, this provision will impose a small cost to Exchanges that have implemented plan category limitations, because it will require a change to application and plan selection system logic to permit applicable enrollees and dependents to change to gold or bronze level plans after having previously restricted them to silver level plans. We solicited comments on the extent to which Exchanges would experience burden due to the change, and regarding potential burden on FFE Direct Enrollment and Enhanced Direct Enrollment partners, as well as more generally on the impact of the proposal.

Several commenters supported providing State Exchanges with flexibility related to implementing special enrollment period policy changes because they often necessitate resource-intensive work. However, a wide range of commenters supported this proposal because they believed it would reduce burden on affected Exchange enrollees by allowing them to change their QHP selection based on a change to their financial circumstances. Some of these commenters noted that this change could allow some enrollees to maintain coverage who otherwise would not have been able to do so, which supports our belief that this provision may have a small but positive impact on the individual market risk pool. Therefore, while we are aware that this change will likely impose burden on State Exchanges required to implement it, we believe that the benefit

of finalizing it will outweigh the cost and that delaying the effective date for this modification will give Exchanges sufficient time to incorporate it into their development priorities and allocate resources accordingly.

b. Special Enrollment Period Limitations for Enrollees Who Are Dependents

We believe that the new provision in § 155.420(a)(4)(iii)(C) will not impose burden on Exchanges, because it will streamline the rules at § 155.420(a)(4) by ensuring that all existing enrollees are treated in the same way, and therefore, may simplify implementation. We also anticipate that it will help mitigate confusion on the part of issuers, Exchanges, and consumers by clarifying that the 2017 Market Stabilization Rule's intent was to apply the same limitations to dependents who are currently enrolled in Exchange coverage that it applies to current, non-dependent Exchange enrollees.

However, we solicited comment from Exchanges on whether this is the case, and if not, on the costs that the proposal would impose in terms of updates to application system logic, as well as potential consumer burden based on the number of enrollees who might be affected by this type of plan category limitation.

Several commenters expressed support for this proposal based on its simplification of current regulations. However, several commenters opposed this proposal based on their belief that a parent or guardian should be able to re-evaluate their household's QHP selection based on metal level when newly enrolling in Exchange coverage with currently-enrolled dependents. Additionally, similar to the other plan category limitation-related proposal, we did not receive comments that specifically contradicted our understanding that this change would impose some limited burden on Exchanges, but several commenters cited strong support for providing State Exchanges with flexibility related to implementing special enrollment period policy changes because they often necessitate resource-intensive work. Some of these commenters also voiced strong opposition to plan category limitations more generally. While we are sensitive to State Exchange concerns about the cost of implementing changes to system logic, we believe that the benefit of this provision in terms of simplifying plan category limitation rules and ensuring that these rules work as intended will outweigh the cost.

c. Special Enrollment Period
Prospective Coverage Effective Dates

Our revision to transition special enrollment periods previously following regular effective date rules to instead be effective on the first of the month following plan selection in Exchanges using the Federal platform will improve long-term operational efficiency through standardization for issuers and the Exchanges using the Federal platform, while reducing consumer confusion and minimizing gaps in coverage. We do not expect issuers to incur substantial new costs by aligning these effective dates, as issuers routinely effectuate coverage on the first of the month following plan selection or faster.

Additionally, because billing is tied to effective dates, transitioning to these more expedited effective dates in the Exchanges using the Federal platform will simplify issuer billing practices. Operationalizing the aligned prospective effective dates may reduce system errors and related casework, as well as confusion for consumers, issuers, and caseworker and call center staff based on different rules applying for different scenarios. Also, we believe eliminating the requirement that Exchanges demonstrate that all of their participating QHP issuers agree to effectuate coverage in a shorter timeframe will reduce burden for both issuers and Exchanges. We did not receive comments on this analysis.

d. Special Enrollment Period
Retroactive Coverage Effective Dates

We are eliminating the special rule for retroactive effective dates after an enrollment has been pended due to special enrollment period verification and to simplify applicability of retroactive effective date and binder payment rules to clarify the ability of consumers effectuating enrollments with retroactive effective dates to select prospective coverage by paying only one month's premium. This will improve long-term operational efficiency for issuers and Exchanges, while reducing confusion for consumers, issuers, and caseworker and call center staff based on different rules for different scenarios. We do not expect issuers to incur new costs in streamlining applicability of the retroactive effective date rule. Under previous § 155.400(e)(1)(iii), issuers already received transactions for retroactive coverage and assigned coverage effective dates either retroactively or prospectively based on consumer payments. This change will simply eliminate the complexity for an issuer to have to determine the appropriate binder payment rule to

apply to an enrollment with a retroactive effective date when issuers receive only 1 month's premium. Finally, because issuers, not Exchanges using the Federal platform, are responsible for assigning effective dates based on premium payments received under this policy, Exchanges using the Federal platform will not incur costs based on this change. We did not receive comments on this analysis.

e. Enrollees Covered by a Non-Calendar Year Plan Year QSEHRA

We are amending § 155.420(d)(1)(ii) to codify the special enrollment period available to qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year. We expect that this will impose some burden on Exchanges and off-Exchange individual health insurance issuers that implement pre-enrollment eligibility verification for special enrollment periods due to related updates to the application and the need to train staff that reviews documents from applicants to verify special enrollment period eligibility. However, we believe that this burden will be limited because the "non-calendar year plan year special enrollment period" is already subject to pre-enrollment eligibility verification, and because individuals who qualify may already be enrolled in Exchange coverage, and therefore, not subject to pre-enrollment eligibility verification. We also anticipate that this provision will impose limited burden on FFE Enhanced Direct Enrollment partners, because required changes for these partners will be limited to updating application question wording.

Additionally, while this provision will provide QSEHRA participants an opportunity to change their individual health insurance plan, we believe that uptake will be limited as most eligible employees will likely not want to change to a new QHP during the QHP's plan year because such a change would result in their deductibles and other accumulators re-setting. Similarly, we believe that burden on issuers related to adverse selection will be limited due to low uptake because of the disadvantages to enrollees of changing their coverage during its plan year, and because the special enrollment period at § 155.420(d)(1)(ii) is subject to plan category limitations per § 155.420(a)(4)(iii). We solicited comments on this proposal, including from Exchanges, on implementation burden and costs.

Commenters generally expressed support for this proposal, and we did not receive comments that this change

would create burden for State Exchanges or other key stakeholders.

8. Effective Dates for Terminations
(§ 155.430)

As discussed earlier in the preamble to § 155.430, this provision will align the provision for termination after an enrollee experiences a technical error that does not allow her to terminate her coverage or enrollment through the Exchange with all other enrollee-initiated termination effective date rules under § 155.430. Specifically, at the option of the Exchange, the enrollee will no longer have to provide 14-days advance notice before the termination becomes effective. Exchanges and issuers are not expected to incur new costs by aligning these termination dates, as Exchanges and issuers are both well acquainted with same-day termination transactions. Further, similar to the 2019 updates to § 155.430(d)(2), this provision will retain State Exchange flexibility to choose whether to implement this change. Operationalizing the aligned termination dates might reduce system errors and related casework, as well as confusion for consumers, issuers, and caseworker and call center staff based on contradictory rules for different scenarios.

9. Quality Rating Information Display Standards for Exchanges (§§ 155.1400 and 155.1405)

We are amending §§ 155.1400 and 155.1405 to codify the flexibility for State Exchanges that operate their own eligibility and enrollment platforms, to customize the display of quality rating information on their websites. We expect that this will impose minimal burden on State Exchanges. In particular, these State Exchanges have the choice to pursue this flexibility or to display the quality rating information assigned for each QHP as provided by HHS. Further, a few State Exchanges during the display pilot have already chosen to display quality rating information with some state-specific customizations to incorporate additional state or local information or to modify the names of the QRS quality ratings.

10. FFE and SBE-FP User Fees
(§ 156.50)

For 2021, we considered two alternative proposals. First, we proposed to maintain the FFE and the SBE-FP user fee rates at current levels, 3.0 and 2.5 percent of premiums, respectively. Alternatively, we considered and solicited comment on reducing the user fee rates below the 2020 benefit year levels. If the user fees

are lowered below the 2020 benefit year levels, FFE and SBE–FP user fee transfers from issuers to the Federal Government would be lower compared to those estimated for the prior benefit year.

We are finalizing the FFE user fee rate at 3.0 percent of premiums and the SBE–FP user fee rate at 2.5 percent of premiums, which are the same as the user fee rates for the 2020 benefit year. Therefore, there will be no change in user fee transfers.

11. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We are amending § 156.111(d) and adding a new paragraph (f) to require states to annually report to HHS any state-required benefits in addition to EHB in accordance with § 155.170 that are applicable to QHPs in the individual and/or small group markets. As finalized, if the state does not report to HHS its state-required benefits considered to be in addition to EHB by the annual reporting submission deadline, HHS will identify which benefits are in addition to EHB for the state for the applicable plan year. We also specify at § 156.111(f)(1) through (6) the type of documentation states will be required to submit as part of the annual reporting, which among other requirements will need to be signed by a state official with authority to make the submission on behalf of the state, to confirm the accuracy of the submission.

Comment: Many commenters stated that an annual reporting requirement would be an additional administrative burden on states, the type the Administration instructed agencies to reduce to the maximum extent permitted by law and duplicate the burden states already bear as the entities responsible for identifying which mandates require defrayal. To ease burden, one commenter recommended that HHS leverage the existing reporting related to EHB rather than creating a new, duplicative report. For example, one commenter stated that HHS making determinations in the states' place about which state-required benefits are in addition to EHB conflicts with Executive Order 13865, "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients," which directs HHS "to the maximum extent permitted by law, provide relief from any provision or requirement of the PPACA that would impose a fiscal burden on any

State. . . ." ¹⁷⁶ Commenters also expressed concern that the annual reporting requirement will be so burdensome that it will discourage states from adopting changes to provide additional health benefits to consumers or even deter states from updating their EHB-benchmark plan.

Response: We recognize that requiring states to annually report to HHS will require that states submit additional paperwork to HHS on an annual basis. However, because states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of those benefits, we believe any burden experienced by states will be minimal and that this reporting requirement will be complementary to the process the state should already have in place for tracking and analyzing state-required benefits. Additionally, states may opt not to report this information and instead let HHS make this determination for them.

We also believe any such burden is justified to ensure that HHS is not paying APTC for portions of premium attributable to non-EHB. We continue to be concerned that there are states not defraying the costs of their state-required benefits in addition to EHB in accordance with Federal requirements. For such states, the burden may be higher to meet the annual reporting requirement to the extent it requires the state to begin tracking, analyzing, and identifying state-required benefits for purposes of determining whether defrayal is required. However, we believe the annual reporting requirement is necessary to help states be diligent about their framework for determining which mandates are in addition to EHB in accordance with § 155.170 and to partner with HHS on improving program integrity. This requirement properly aligns with Federal requirements for defraying the cost of state-mandated benefits, will generally improve transparency with regard to the types of benefit requirements states are enacting, and will provide the necessary information to HHS for increased oversight over whether states are appropriately determining 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.

¹⁷⁶ Executive Order 13865, "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients," 82 FR 26885, 26886 (June 12, 2017) available at <https://www.govinfo.gov/content/pkg/FR-2017-06-12/pdf/2017-12130.pdf>.

We acknowledge that some states may already be appropriately identifying which state-required benefits are in addition to EHB, and that these states may have already developed an effective process for defraying the cost of these state-required benefits. However, we believe many other states are not doing so, and that this annual reporting policy will assist in achieving greater compliance with § 155.170 in all states, and therefore, broadly strengthen program integrity. Furthermore, we disagree that requiring already compliant states to annually report would be disruptive or unnecessarily burdensome given that the information included in the annual reports should already be readily accessible to states, especially already compliant states. We believe any burden will be limited to the completion of the HHS templates, validation of that information, and submission of the templates to HHS. These costs have been discussed previously in the Collection of Information Requirements section. We also believe standardizing the form and manner of the report and the data elements required (rather than allowing states to determine the form and manner of reporting) is important for consistency year after year and for ensuring HHS has the information necessary to adequately oversee state compliance with § 155.170.

We do not anticipate these requirements will add any new burden on non-reporting states as they will be relying on HHS to make these determinations and fill out these templates for them. Because we are also finalizing that HHS's identification of which benefits are in addition to EHB in non-reporting states will become part of the definition of EHB for the applicable state for the applicable year, this may require states to defray more benefits than the state currently defrays or anticipated having to defray. In this scenario, we acknowledge the annual reporting requirement may generate additional costs for a state that defers the task of identifying state-mandated benefits that require defrayal to HHS in order to properly align the state with Federal requirements regarding defrayal.

To the extent that this provision will cause a state to newly defray the cost of state-required benefits, this will represent a transfer of costs from the issuer to the state, as the issuer might have been previously covering the costs of benefits for which the state should have been defraying. In the event that the annual reporting requirement causes states to newly identify state-required benefits as being in addition to EHB that were previously being incorrectly

covered as part of EHB, this may decrease the amount of PTC for enrollees in the state as the percent of premium allocable to EHB will be reduced.

We again emphasize that 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 a PTC. As such, we believe any burden resulting from the finalized annual reporting requirement is necessary to ensure that the federal government is not paying APTC for portions of premiums attributable to non-EHB in violation of this provision.

12. Provisions Related to Cost Sharing (§ 156.130)

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance is intended to help many low- and moderate-income individuals and families obtain health insurance.

We are finalizing the reductions in the maximum annual limitation on cost sharing for silver plan variations as proposed. Consistent with our analysis in previous Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the PPACA to the estimated 2021 maximum annual limitation on cost sharing for self only coverage of \$8,550. We do not believe the changes to the maximum annual limitation on cost sharing or the reductions in this parameter for silver plan variations will result in a significant economic impact.

We are also finalizing the premium adjustment percentage for the 2021 benefit year at the proposed value of 1.3542376277, based on the NHEA data available at the time of proposal. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the Affordable Care Act: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b). In response to comments, we have finalized the premium adjustment percentage, required contribution

percentage, and related parameters based on the NHEA data that were available as of the publication of the proposed rule. This approach differs from the approach taken by HHS in the 2020 Payment Notice, wherein we updated the premium adjustment percentage based on updates to the NHEA data that took place between the publication of the proposed rule and the publication of the final rule.

We are finalizing the 2021 premium adjustment percentage as proposed without updates to reflect the most recent NHEA data available as of the publication of the proposed rule in order to increase the transparency and predictability of premium adjustment percentage and related parameters for stakeholders.

We believe that the premium adjustment percentage of 1.3542376277 based on average per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance), and as calculated based on NHEA data available as of the publication of the proposed rule, is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these finalized values will alter CBO's May 2018 baseline estimates of the budget impact beyond the changes described in the 2020 Payment Notice.

13. Cost-Sharing Requirements and Drug Manufacturers Support (§ 156.130)

We are revising § 156.130(h) in its entirety to state, notwithstanding any other provision of the annual limitation on cost sharing regulation, and to the extent consistent with state law, amounts of direct support offered by drug manufacturers to enrollees for specific prescription drugs towards reducing the cost sharing incurred by an enrollee using any form are not required to be counted toward the annual limitation on cost sharing. We believe that this will impose minimal burden, as it reflects the longstanding practice of health insurance issuers and group health plans determining whether drug manufacturer direct support to enrollees for specific prescription drugs counts toward the annual limitation on cost sharing.

Comment: Some commenters expressed concerns that consumers would experience higher health care utilization and greater overall health care costs.

Response: While we appreciate concerns that the proposal may raise out-of-pocket costs for consumers, we believe the impact of such costs will be limited as issuers and group health plans were provided with sufficient

notice that longstanding plan designs need not change for plan year 2020 with regard to how direct drug manufacturer support amounts count towards the annual limitation on cost sharing. By finalizing this policy, issuers and group health plans may continue their longstanding practices with regard to how and whether direct drug manufacturer support accrues towards an enrollee's annual limitation on cost sharing. This, combined with FAQ Part 40 released in August 2019, should prevent or mitigate changes to how issuers and group health plans have historically handled direct drug manufacturer support amounts. Therefore, we anticipate that there will be minimal overall disruption to consumers.

14. Requirements for Timely Submission of Enrollment Reconciliation Data (§ 156.265)

In the Establishment of Exchanges and Qualified Health Plans; Exchange Standards interim final rule,¹⁷⁷ we established standards for the collection and transmission of enrollment information. At § 156.265(f), we set forth standards on the enrollment reconciliation process, specifying that issuers must reconcile enrollment with the Exchange no less than once a month. Although the regulations in § 156.265 require issuers to reconcile enrollment with the Exchange monthly, they do not specify standards for the format or quality of these data exchanges, such as the manner in which enrollment updates must be reflected in updates of previously submitted enrollment data, or the timeframe in which issuers should report data updates and data errors to the Exchange. To clarify these procedures, we are amending § 156.265(f) to require a QHP issuer to include in its enrollment reconciliation submission to the Exchange the most recent enrollment information that is available and that has been verified to the best of its knowledge or belief. We are also amending § 156.265(g) to direct a QHP issuer to update its enrollment records as directed by the Exchange (or for QHP issuers in SBE-FPs, the Federal platform), and to inform the Exchange (or for QHP issuers in SBE-FPs, the Federal platform) if any such directions are in error within 30 days. In SBE-FPs, references in this section to the Exchange should be understood to mean HHS, as administrator of the Federal platform. We believe these amendments will encourage more timely reconciliation and error reporting, resulting in an improved consumer

¹⁷⁷ See 77 FR 18309 at 18425.

experience. However, because we believe that issuers are already routinely conducting verifications of internal enrollment data at various points in the year, we do not believe that these clarifying standards on the process for submitting enrollment and reconciliation data will materially impact issuer burden, beyond what we estimated in the Exchange Establishment rules.

15. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice,¹⁷⁸ we established provisions related to confirmation and dispute of payment and collection reports. These provisions were written under the assumption that issuers would generally be able to provide these confirmations or disputes automatically to HHS. We are amending § 156.1210 by lengthening the time to report payment errors from 15 days to 90 days to allow issuers the option of researching, reporting, and correcting errors through other channels. We believe this change will slightly reduce issuer burden compared to what was previously estimated in the 2014 Payment Notice.

16. Medical Loss Ratio (§§ 158.110, 158.140, 158.150, and 158.160)

We are amending § 158.110(a) to clarify that for MLR purposes, issuers must report expenses for functions outsourced to or services provided by other entities consistently with how issuers must report directly incurred expenses. We do not expect this amendment to impact issuer burden as it does not fundamentally change the existing requirements. We are also amending § 158.140(b)(1)(i) to require issuers to deduct from incurred claims not only the prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer, as well as any prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer. We are making conforming amendments to § 158.160(b)(2) to require such amounts to be reported as non-claims costs when received and retained by an entity providing pharmacy benefit management services. While there does not exist comprehensive public data on the amount, prevalence, or retention rate for prescription drug rebates and other price concessions retained by PBMs or other entities providing pharmacy benefit management services,

based on data from the 2017 MLR reporting year, including the data from issuers who receive and report prescription drug rebates, we estimate that this requirement may increase rebate payments from issuers to consumers by \$18.4 million per year. Since issuers generally prefer to set premium rates at a level that avoids rebates, and consequently potential rebate increases create a downward pressure on premiums, this requirement is also likely to lead to reductions in PTC transfers (which are a function of the premium rate for the second lowest-cost silver plan applicable to a consumer, the premium rate for the plan purchased by the consumer, and the consumer's income level) from the Federal Government to certain consumers in the individual market. Additionally, we are amending § 158.150(b)(2)(iv)(A)(5) to explicitly allow issuers in the individual market to include the cost of certain wellness incentives as QIA in the MLR calculation. Based on data from the 2017 MLR reporting year, we estimate that this provision may decrease rebate payments from issuers to consumers by \$0.2 million per year.

We are finalizing these proposals as proposed, except that we are delaying the applicability date of the amendments to §§ 158.140(b)(1)(i) and 158.160(b)(2) until the 2022 MLR reporting year (MLR reports filed in 2023), and modifying the amendment to § 158.160(b)(2) to only apply to the prescription drug rebates and price concessions received and retained by an entity providing pharmacy benefit management services to the issuer.

Comment: One commenter stated that the amendment to § 158.140(b)(1)(i) requiring issuers to deduct from incurred claims the prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services to the issuer would increase, rather than decrease, premiums because “retained rebates as currently reported under MLR reduce actual plan administrative expenses [and t]he administrative fees paid to PBMs that replace the retained rebates would also be subtracted, resulting in the same net effect.”

Response: We respectfully disagree with the commenter's assessment. We note that the regulation, both before and after the amendment to § 158.140(b)(1)(i), does not allow administrative fees paid by an issuer directly to a PBM or a similar entity to be included in incurred claims. However, prior to the amendment to § 158.140(b)(1)(i), an issuer was able to

include in incurred claims compensation provided by an issuer to a PBM for administrative or other services by allowing the PBM to retain part or all of the prescription drug rebates and other price concessions. Because the amendment to § 158.140(b)(1)(i) requires issuers to subtract such prescription drug rebates and other price concessions from incurred claims, the amendment will result in lower MLRs for some issuers and will lead such issuers to lower premiums or pay higher MLR rebates to enrollees.

17. 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, non-Federal governmental entities offering excepted benefit HRAs, 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 consider the number of affected entities and past commenters to be a fair estimate of the number of reviewers of this final 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 \$109.36 per hour, including overhead and fringe benefits.¹⁷⁹ Assuming an average reading speed, we estimate that it would take approximately 1 hours for the staff to review the relevant portions

¹⁷⁸ See 78 FR 65045 at 65080.

¹⁷⁹ https://www.bls.gov/oes/current/oes_nat.htm.

of this final rule that causes unanticipated burden. We assume that approximately 1,550 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately \$109.36. Therefore, we estimate that the total cost of reviewing this regulation is approximately \$169,508 ($\$109.36 \times 1,550$ reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

For the amendment to part 146, we considered not proposing a requirement that a notice be provided to individuals with an offer of an excepted benefit HRA from a non-Federal governmental plan. However, we believe that a notice will provide these consumers with important information about their excepted benefit HRA.

Instead of deleting the regulations in part 149, governing the ERRP, we considered taking no action and leaving the regulations in place. We believe that it serves the public interest to reduce the volume of federal regulations when doing so will not compromise the effectiveness of federal programs, nor detract from the government's ability to implement laws or oversee funds appropriated for that purpose. Since the ERRP has been fully implemented, and has no ongoing functions, costs, or obligations, repealing the regulations will not impair the government's ability to implement the program or oversee the funds appropriated for that purpose.

In finalizing the risk adjustment model recalibration in part 153, we considered whether to add an additional sex and age category for enrollees age 65 and over as part of our recalibration of the HHS models, due to our proposal to stop using MarketScan® data. However, upon finding different trends in the age 65 and over population, as discussed in the preamble, we did not propose to add these additional categories.

In regards to the proposed 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.

Regarding the changes to §§ 155.330 and 155.430, we considered taking no action to clarify Exchange operations regarding processing voluntary terminations for Exchange enrollees who provide written consent to permit the Exchange to end QHP coverage if they are later found to also be enrolled in Medicare via PDM. We ultimately determined however that these revisions were necessary to clarify that eligibility need not be redetermined as part of terminations at the request of enrollees resulting from Medicare PDM.

Additionally, we considered taking no action and proceeding with terminating coverage following an eligibility determination when the Exchange conducts periodic checks for deceased enrollees rather than retroactively terminating back to the date of death. However, we determined that the revisions will clarify that eligibility need not be redetermined prior to terminating deceased enrollee coverage retroactively to the date of death.

We considered taking no action regarding the proposal to add a new § 155.420(a)(4)(ii)(B) in order to allow enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment. However, based on questions and concerns from Navigators and other enrollment assisters, as well as from agents and brokers, the current policy likely prevents some enrollees from maintaining continuous coverage for themselves and for their dependents due to a potentially significant change to their out-of-pocket costs. Under the provision, an enrollee impacted by an increase to his or her monthly premium payment may change to a bronze-level plan, while an enrollee who has concerns about higher copayment or coinsurance cost-sharing requirements may change to a gold-level plan. HHS believes that this policy will likely have minimal impact on the individual market risk pool because most applicable enrollees will be seeking to change coverage based on changes to

their financial circumstances rather than ongoing or emerging health needs.

We also considered making no changes regarding our proposal to clarify the 2017 Market Stabilization Rule's intent to apply the same limitations to dependents who are currently enrolled in Exchange coverage that it applies to current, non-dependent Exchange enrollees. As discussed in the proposed rule, preamble language from the 2017 Market Stabilization Proposed Rule explains that the requirement at § 155.420(a)(4)(iii) would extend to enrollees who are on an application where a new applicant is enrolling in coverage through a special enrollment period, using general terms to convey that restrictions should apply to enrollees and newly-enrolling individuals regardless of the dependent or parent or guardian status of a new enrollee. However, because this intended aspect of the limitation is not articulated in regulation, we were concerned that the rule's current wording would cause confusion among issuers, consumers, and Exchanges. Additionally, this change is consistent with HHS's goal to establish equivalent treatment for all special enrollment period eligible enrollees, and with the policy goal of preventing enrollees from changing plans in the middle of the coverage year based on ongoing or newly emerging health issues.

In proposing and finalizing that special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection in Exchanges using the Federal platform, we considered whether we could implement this change through subregulatory guidance, since for many of these special enrollment periods, Exchanges have discretion under § 155.420(b)(2)(i), (iv), and (v) to provide an effective date on the first of the month following plan selection, or under § 155.420(b)(3) to ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period. However, Exchange discretion is not available under current regulations for several special enrollment periods that use regular effective dates; that is, HHS could not apply faster effective dates in the Exchanges using the Federal platform without regulatory changes for certain special enrollment periods. These are the special enrollment periods available under § 155.420(d)(6)(i), (ii), and (v); (d)(8); and (d)(10). Only applying faster effective dates for some, but not all, special enrollment periods that currently use regular effective date rules would not accomplish our goals of

standardization and improving long-term operational efficiency. We believe this regulatory change is necessary to align all prospective special enrollment periods under one effective date rule.

In proposing and finalizing aligning retroactive effective date and binder payment rules under § 155.400(e)(1)(iii), we considered eliminating both § 155.400(e)(1)(v) (as we proposed), but revising, rather than eliminating, § 155.420(b)(5). Previously, section 155.420(b)(5) provided that if a consumer's enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, and the assigned effective date would require the consumer to pay 2 or more months of retroactive premium to effectuate coverage or avoid cancellation, the consumer has the option to choose a coverage effective date that is no more than 1 month later than had previously been assigned. However, we determined that revising this provision would cause more confusion than standardizing retroactive effective date and binder payment rules under § 155.400(e)(1)(iii). Instead, we are finalizing the proposed amendment to § 155.400(e)(1)(iii) to state more explicitly that any consumer who can effectuate coverage with a retroactive effective date, including those whose enrollment is delayed until after special enrollment period verification, would also have the option to effectuate coverage with the applicable prospective coverage.

Through this change, a consumer can choose to only pay for 1 month of coverage by the applicable deadline, notwithstanding the retroactive effective date that the Exchange otherwise would be required to ensure. Even though very few consumers wait more than a few days for HHS to review their special enrollment period verification documents and provide a response (as discussed in the preamble of the proposed rule), we want to ensure that those few consumers whose coverage is delayed by at least 1 month due to special enrollment period verification would have the same options as any other consumers who are eligible to receive coverage with a retroactive effective date.

As described in the HRA rule,¹⁸⁰ HHS included consumers who are newly provided a QSEHRA in the class of persons eligible for a new special enrollment period established for qualified individuals, enrollees, and dependents who newly gain access to an individual coverage HRA. We also expressed our intent to treat a QSEHRA

with a non-calendar year plan year as a group health plan for the limited purpose of the non-calendar year plan year special enrollment period, and to codify this interpretation in future rulemaking. Our goal is to ensure employees and their dependents with a non-calendar year plan year QSEHRA have the same opportunity to change individual health insurance coverage outside of the individual market open enrollment period as those who are enrolled in a non-calendar year plan year individual coverage HRA.

In finalizing the annual reporting of state-required benefits in addition to EHB, we considered a variety of alternatives, including withdrawing the proposal altogether. We also considered instead issuing a toolkit or guidance for states to assist with identifying state-required benefits in addition to EHB and properly defraying the cost of those benefits in accordance with § 155.170. However, we do not believe that either of these options would alone offer HHS direct insight into the frequency with which states require benefits in addition to EHB to be covered and whether states are properly defraying the costs of state-required benefits in addition to EHB. Therefore, we are finalizing the annual reporting policy as proposed, except for a minor revision at § 156.111(d)(2). However, to address comments regarding the lack of clarity around the current defrayal policy, we will also take steps to engage with states to clarify this policy before the first annual submission deadline. Through this state engagement, we hope to provide additional technical assistance that helps ensure state understanding when a state-benefit requirement is in addition to EHB and requires defrayal, provides examples, and explains how a state could operationalize the defrayal process pursuant to federal requirements at § 155.170. We believe additional outreach to states prior to the first annual reporting submission deadline of July 1, 2021, will strengthen state understanding of defrayal policy ahead of the first year of implementation of the annual reporting requirement in plan year 2021.

We also considered revising the policy such that Exchanges would again be the entity responsible for identifying which additional state-required benefits, if any, are in addition to EHB instead of the state. However, as noted previously in the 2017 Payment Notice, we changed the policy to make the state the entity responsible for identifying state-required benefits in addition to EHB instead of the Exchange because we believe states are generally more familiar with state-required benefits. We

also considered revising § 155.170 to make HHS the entity responsible for identifying which state-required benefits are in addition to EHB in every state such that HHS would always identify which mandates require defrayal, but the QHP issuers would still be responsible for quantifying the costs for these additional mandates and reporting them to the state, at which point the state would be expected to make payments directly to the enrollee or the QHP issuer. However, because we still believe states are generally most familiar with state-required benefits and, because we support state flexibility, we believe that states should remain the entity responsible for identifying state-required benefits in addition to EHB. We believe the annual reporting policy we are finalizing is consistent with this goal of state flexibility and acknowledges state expertise, as it would not shift the authority from the state to HHS as the entity responsible for identifying whether a mandate is in addition to EHB unless the state does not submit an annual report to HHS or does not do so in the form and manner specified by HHS, in which case only then would HHS identify which state-required benefits are in addition to EHB for the state.

In proposing and finalizing amendments to § 156.270(b)(1) to require QHP issuers to send to enrollees a termination notice for all termination events, we considered whether to revert to the original language in the first iteration of § 156.270, which required a termination notice when an enrollee's coverage was terminated "for any reason." However, because the termination notice requirement is triggered under this paragraph "[i]f a QHP issuer terminates an enrollee's coverage or enrollment in a QHP through the Exchange . . .," we were concerned that this could be read to require termination notices for issuer-initiated terminations only. To be clear that we are proposing to require termination notices for the full range of termination events described under § 155.430(b), including those initiated by an enrollee, our amendments instead refer broadly to the reasons listed in § 155.430(b) rather than identifying each termination reason under that section.

For the amendments to § 158.150, we considered making no change to the current regulation that does not explicitly allow issuers in the individual market to include the cost of certain wellness incentives as QIA in the MLR calculation. However, we believe that finalizing the changes to this section will ensure that it is

¹⁸⁰ 84 FR 28888.

interpreted consistently across the individual and group markets. We also believe that finalizing the changes to this section will generally increase consumer choice and access to wellness programs, including any health-contingent wellness programs that may be available in a state that is approved to participate in the wellness program demonstration project.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity”. HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this rule, we finalize standards for the risk adjustment and RADV programs, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$35 million or less.¹⁸¹ 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 report¹⁸² submissions for the 2017 MLR reporting year, approximately 90 out of 500 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 72 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. Only 10 of these 90 potentially small entities, three of them part of larger holding groups, are estimated to experience a change in rebates under the amendments to the MLR provisions of this final rule in part 158. Therefore, we believe that the MLR provisions of this final rule will not affect a substantial number of small entities.

We believe that a small number of non-Federal government jurisdictions with a population of less than 50,000 will offer employees an excepted benefit HRA, and therefore, will be subject to the proposed notice requirement in part 146. Therefore, we do not believe that an initial regulatory flexibility analysis is required for such firms.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule will not affect small rural hospitals. Therefore, the Secretary has 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 proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156

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 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. Current State Exchanges charge user fees to issuers.

In our view, while this final rule will not impose substantial direct requirements or 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. We are also requiring non-Federal governmental plan sponsors to provide a notice when offering an excepted benefit HRA, but expect state and local governments to incur minimal costs to meet the requirements in this rule.

¹⁸¹ <https://www.sba.gov/document/support-table-size-standards>.

¹⁸² Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

We also believe this regulation has federalism implications for the PDM process provisions, specifically for QHP terminations resulting from Medicare, Medicaid/CHIP, BHP (if applicable) or deceased enrollee PDM. In these instances, HHS also believes that the federalism implications are substantially mitigated because the requirements merely clarify that the Exchange is following termination guidelines that differ from the processes when Exchanges are terminating only APTC/CSRs as part of the standard PDM processes. Furthermore, these clarifications will not impose new requirements on State Exchanges that operate their own eligibility and enrollment platform, but rather provide guidance that State Exchanges that operate their own eligibility and enrollment platform can choose to incorporate into their current operations for PDM.

We believe there may be federalism implications in connection with our provisions related to plan category limitations: (1) We added a new § 155.420(a)(4)(ii)(B) in order to allow enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP, to select a QHP one metal level higher or lower if they elect to change their QHP enrollment; and (2) we added a new § 155.420(a)(4)(iii)(C) to apply the same limitations to dependents who are currently enrolled in Exchange coverage that it applies to current, non-dependent Exchange enrollees. There may be operational costs to State Exchanges that have already implemented plan category limitations due to the need to update their application logic to reflect these changes. However, given the 2017 Market Stabilization Rule preamble language discussed above, it is possible that State Exchanges are already in compliance with our proposal to clarify the application of the same limitations to dependents who are currently enrolled in Exchange coverage that apply to current, non-dependent Exchange enrollees. We solicited comment on how many State Exchanges currently implement plan category limitations, as well as estimates related to how much time and expense would be required to update these systems to comply with the two proposals.

Comment: We did not receive comments describing State Exchanges' implementation of plan category limitations, or comments that included estimates of time and expense that this proposal would require. However, several commenters expressed support for providing State Exchanges with flexibility related to special enrollment

period policy implementation in general, explaining that any special enrollment period changes require significant State Exchange effort and potentially unpredictable costs.

Response: Given most commenters' support for allowing enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP, to select a QHP one metal level higher or lower if they elect to change their QHP enrollment, we believe that the benefits of finalizing it as proposed outweigh general concerns about implementation. Additionally, we have delayed the effective date for this modification to January 2022, which we believe will allow Exchanges sufficient time to incorporate the change into their development priorities. We also believe that the benefit of simplifying plan category limitation rules and ensuring that these rules work as intended by applying the same limitations to enrolled dependents that apply to non-dependents will outweigh costs associated with implementation.

Additionally, we expect that amendment to § 155.420(d)(1)(ii) to codify the special enrollment period for qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year will have some federalism implications, because it will require State Exchanges to update the wording of their applications, and to update instructions for verifying a special enrollment period due to a loss of MEC to include applicants with a non-calendar year plan year QSEHRA. Additionally, State Exchanges, as well as FFE Direct Enrollment and Enhanced Direct Enrollment partners, may see a nominal increase in the number of consumers obtaining coverage through the non-calendar year plan year special enrollment period at § 155.420(d)(1)(ii). However, we expect this number to be low.

We do not anticipate any federalism implications related to our revision providing that special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection in the Exchanges using the Federal platform. We believe State Exchanges are best positioned to determine which effective date rules meet the needs of their issuers and consumers. As such, under our changes, State Exchanges may retain their current effective date rules or implement faster ones without needing to demonstrate issuer concurrence.

We do not expect there to be federalism implications related to removing the separate retroactive effective date rule for enrollments

pending due to special enrollment period verification under § 155.420(b)(5). Neither the retroactive binder payment rule specific to enrollments pending due to special enrollment period eligibility verification at § 155.400(e)(1)(v), nor the original retroactive binder payment rule at § 155.400(e)(1)(iii), applies outside of Exchanges using the Federal platform. Although previous § 155.420(b)(5) did apply to State Exchanges, a State Exchange that has implemented special enrollment period verification will retain flexibility to apply the policy that if a consumer's enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, and the assigned effective date would require the consumer to pay 2 or more months of retroactive premium to effectuate coverage or avoid cancellation, the consumer has the option to choose a coverage effective date that is no more than 1 month later than had previously been assigned.

We do not anticipate any federalism implications related to our requirement for QHP issuers to send to enrollees a termination notice for all termination events described in § 155.430(b).

We do not anticipate any federalism implications related to our provision described in § 155.430(d) to align the provision for termination after experiencing a technical error that did not allow the enrollee to terminate his or her coverage or enrollment through the Exchange with all other enrollee-initiated termination effective date rules under § 155.430 that, at the option of the Exchange, no longer require 14-days advance notice.

We continue to believe there may be federalism implications related to the requirement we are finalizing that states annually report to HHS, in a form and manner specified by HHS, any state-required benefits in addition to EHB in accordance with § 155.170 that are applicable to QHPs in the individual and/or small group market. States that do not report to HHS their required benefits considered to be in addition to EHB by the annual reporting submission deadline, or do not do so in the form and manner specified by HHS, will be relying on HHS to identify such benefits. We acknowledge that the state-required benefits HHS identifies as in addition to EHB and that therefore require defrayal, might conflict with the opinion of a state that does not annually report to HHS. However, such concerns are mitigated because states can avoid such a result by submitting the report. Further, as previously noted, HHS must ensure that APTC is paid in accordance

with federal law. If a state is not defraying the cost of a state-required benefit that is in addition to EHB, resulting in improper federal expenditures, we believe section 1313(a)(4) of the PPACA empowers HHS to take action consistent with its enforcement authorities to address a state's failure to comply with the PPACA's defrayal requirements. However, as also noted earlier in the preamble, we intend to continue the collaborative process we have cultivated with states up to this point, and to provide non-reporting states with an opportunity to review our identifications prior to releasing the annual reports on the CMS website for public viewing in an effort to mitigate the potential for disagreement between the state and HHS.

H. Congressional Review Act

This rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information. Therefore, the rule has been transmitted to the Congress and the Comptroller. 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. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

This final rule is an E.O. 13771 deregulatory action. We estimate cost savings of approximately \$147.15 million in 2020 and \$98.89 million in 2021 and annual costs of approximately \$59,000 thereafter. Thus the annualized

value of cost savings, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, is \$11.40 million.

List of Subjects

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 149

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, 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 amends 45 CFR subtitle A, subchapter B, as set forth below.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300–gg–92.

■ 2. Section 146.145 is amended by adding paragraph (b)(3)(viii)(E) to read as follows:

§ 146.145 Special rules relating to group health plans.

* * * * *

(b) * * *

(3) * * *

(viii) * * *

(E) *Notice requirement.* For plan years beginning on or after January 11, 2021, the HRA or other account-based group health plan must provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps, or other limits on benefits under the plan, and a description or summary of the benefits. This notice must be provided no later than 90 days after an employee becomes a participant and annually thereafter, in a manner reasonably calculated to ensure actual receipt by participants eligible for the HRA or other account-based group health plan.

* * * * *

PART 149—[REMOVED and RESERVED]

■ 3. Part 149 is removed and reserved.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 4. 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.

■ 5. Section 155.330 is amended by revising paragraph (e)(2)(i)(D) to read as follows:

§ 155.330 Eligibility redetermination during a benefit year.

* * * * *

(e) * * *

(2) * * *

(i) * * *

(D) If the enrollee does not respond contesting the updated information within the 30-day period specified in paragraph (e)(2)(i)(B) of this section, proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section, provided the enrollee has not directed the Exchange to terminate his or her coverage under such circumstances, in which case the Exchange will terminate the enrollee's coverage in accordance with § 155.430(b)(1)(ii), and provided the enrollee has not been determined to

be deceased, in which case the Exchange will terminate the enrollee's coverage in accordance with § 155.430(d)(7).

■ 6. Section 155.400 is amended by revising paragraphs (e)(1)(i) through (iii) and removing paragraph (e)(1)(iv) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

- (e) * * *
(1) * * *

(i) For prospective coverage to be effectuated under regular coverage effective dates, as provided for in § 155.410(f), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date, and no later than 30 calendar days from the coverage effective date.

(ii) For prospective coverage to be effectuated under special effective dates, as provided for in § 155.420(b)(2) and (3), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date and no later than 30 calendar days from the date the issuer receives the enrollment transaction or the coverage effective date, whichever is later.

(iii) For coverage to be effectuated under retroactive effective dates, as provided for in § 155.420(b)(2), including when retroactive effective dates are due to a delay until after special enrollment period verification, the binder payment must consist of the premium due for all months of retroactive coverage through the first prospective month of coverage, and the deadline for making the binder payment must be no earlier than 30 calendar days from the date the issuer receives the enrollment transaction. If only the premium for 1 month of coverage is paid, only prospective coverage should be effectuated, in accordance with § 155.420(b)(3).

* * * * *

■ 7. Section 155.420 is amended by—
■ a. Revising paragraphs (a)(4)(ii) and (iii), (b)(1) introductory text, and (b)(3);
■ b. Removing paragraph (b)(5); and
■ c. Revising paragraph (d)(1)(ii).
The revisions and addition read as follows:

§ 155.420 Special enrollment periods.

- (a) * * *
(4) * * *

(ii)(A) If an enrollee and his or her dependents become newly eligible for

cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are not enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a silver-level QHP if they elect to change their QHP enrollment; or

(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.

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), and (d)(6)(i) and (ii) of this section for becoming newly eligible or ineligible for CSRs and paragraphs (d)(8), (9), (10), (12), and (14) of this section:

(A) If an enrollee qualifies for a special enrollment period, the Exchange must allow the enrollee and his or her dependents, if applicable, to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter;

(B) If a dependent qualifies for a special enrollment period, and an enrollee who does not also qualify for a special enrollment period is adding the dependent to his or her QHP, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter, or enroll the new qualified individual in a separate QHP; or

(C) If a qualified individual who is not an enrollee qualifies for a special enrollment period and has one or more dependents who are enrollees who do not also qualify for a special enrollment period, the Exchange must allow the newly enrolling qualified individual to add himself or herself to a dependent's current QHP; or, if the QHP's business rules do not allow the qualified individual to enroll in the dependent's current QHP, to enroll with his or her dependent(s) in another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of

this subchapter, or enroll himself or herself in a separate QHP.

* * * * *

- (b) * * *

(1) Regular effective dates. Except as specified in paragraphs (b)(2) and (3) of this section, for a QHP selection received by the Exchange from a qualified individual—

* * * * *

- (3) Option for earlier effective dates.

(i) For a QHP selection received by the Exchange under a special enrollment period for which regular effective dates specified in paragraph (b)(1) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph, and, beginning January 2022, a Federally-facilitated Exchange or a State Exchange on the Federal platform will ensure that coverage is effective on the first day of the month following plan selection.

(ii) For a QHP selection received by the Exchange under a special enrollment period for which special effective dates specified in paragraph (b)(2)(ii) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

* * * * *

- (d) * * *
(1) * * *

(ii) Is enrolled in any non-calendar year group health plan, individual health insurance coverage, or qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code); even if the qualified individual or his or her dependent has the option to renew or re-enroll in such coverage. The date of the loss of coverage is the last day of the plan year;

* * * * *

■ 8. Section 155.430 is amended by revising paragraphs (b)(1)(ii) and (d)(9) to read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

- (b) * * *
(1) * * *

(ii) The Exchange must provide an opportunity at the time of plan selection for an enrollee to choose to remain enrolled in a QHP if he or she becomes eligible for other minimum essential coverage and the enrollee does not request termination in accordance with paragraph (b)(1)(i) of this section. If an enrollee does not choose to remain enrolled in a QHP in such situation, the Exchange must initiate termination of his or her enrollment in the QHP upon

completion of the process specified in § 155.330(e)(2).

* * * * *

(d) * * *

(9) In case of a retroactive termination in accordance with paragraph (b)(1)(iv)(A) of this section, the termination date will be no sooner than the date that would have applied under paragraph (d)(2) of this section, based on the date that the enrollee can demonstrate he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, had the technical error not occurred.

* * * * *

■ 9. Section 155.1400 is revised to read as follows:

§ 155.1400 Quality rating system.

The Exchange must prominently display quality rating information for each QHP on its website, in accordance with § 155.205(b)(1)(v), in a form and manner specified by HHS.

■ 10. Section 155.1405 is revised to read as follows:

§ 155.1405 Enrollee satisfaction survey system.

The Exchange must prominently display results from the Enrollee Satisfaction Survey for each QHP on its website, in accordance with § 155.205(b)(1)(iv), in a form and manner specified by HHS.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 11. 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.

§ 156.20 [Amended]

■ 12. Section 156.20 is amended by removing the definition of “Generic”.

■ 13. Section 156.111 is amended by—

- a. Revising the section heading and paragraph (d) introductory text; and
- b. Adding paragraphs (d)(2) and (f).

The revisions and additions read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020, and annual reporting of state-required benefits.

* * * * *

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by a date to be determined by HHS for each applicable plan year and, in

accordance with paragraph (f) of this section, of any State-required benefits that are in addition to EHB identified under § 155.170(a)(3) of this subchapter.

* * * * *

(2) If the State does not notify HHS of its State-required benefits that are in addition to EHB identified under § 155.170(a)(3) of this subchapter in accordance with paragraph (f) of this section, HHS will identify which benefits are in addition to EHB for the applicable plan year in the State, consistent with § 155.170(a)(2) of this subchapter.

* * * * *

(f) A State must submit to HHS in a form and manner and by a date specified by HHS, a document that:

(1) Is accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS and that lists all State benefit requirements applicable to QHPs in the individual and/or small group market under state mandates imposed on or before December 31, 2011, and that were not withdrawn or otherwise no longer effective before December 31, 2011, and any State benefit requirements that were imposed any time after December 31, 2011;

(2) Specifies which of those State-required benefits listed in accordance with paragraph (f)(1) of this section the State has identified as in addition to EHB and subject to defrayal in accordance with § 155.170 of this subchapter;

(3) Specifies which of those State-required benefits listed in accordance with paragraph (f)(1) of this section the State has identified as not in addition to EHB and not subject to defrayal in accordance with § 155.170 of this subchapter, and describes the basis for the state's determination;

(4) Provides other information about those State-required benefits listed in accordance with paragraph (f)(1) of this section that is necessary for HHS oversight, as specified by HHS;

(5) Is signed by a state official with authority to make the submission on behalf of the state certifying the accuracy of the submission; and

(6) Is updated annually, in a form and manner and by a date specified by HHS, to include any new State benefit requirements, and to indicate whether benefit requirements previously reported to HHS under this paragraph (f) have been amended, repealed, or otherwise affected by state regulatory or legislative action.

■ 14. Section 156.130 is amended by revising paragraph (h) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(h) *Use of direct support offered by drug manufacturers.* Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing, as defined in paragraph (a) of this section.

■ 15. Section 156.265 is amended by revising paragraphs (f) and (g) to read as follows:

§ 156.265 Enrollment process for qualified individuals.

* * * * *

(f) *Enrollment reconciliation.* A QHP issuer must reconcile enrollment files with the Exchange in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) and resolve assigned updates no less than once a month in accordance with § 155.400(d) of this subchapter, using the most recent enrollment information that is available and that has been verified to the best of the issuer's knowledge or belief.

(g) *Timely updates to enrollment records.* A QHP issuer offering plans through an Exchange must, in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), either:

(1) Verify to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) that the information in the enrollment reconciliation file received from the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) accurately reflects its enrollment data for the applicable benefit year in its next enrollment reconciliation file submission to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), and update its internal enrollment records accordingly; or

(2) Describe to the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) within one reconciliation cycle any discrepancy it identifies in the enrollment reconciliation files it received from the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform).

■ 16. Section 156.270 is amended by revising paragraph (b) introductory text to read as follows:

§ 156.270 Termination of coverage or enrollment for qualified individuals.

* * * * *

(b) *Termination of coverage or enrollment notice requirement.* If a QHP issuer terminates an enrollee's coverage or enrollment in a QHP through the Exchange in accordance with § 155.430(b) of this subchapter, the QHP issuer must, promptly and without undue delay:

* * * * *

■ 17. Section 156.1210 is revised to 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 describe to HHS any inaccuracies it identifies in the report.

(b) *Confirmation of HHS payment and collections reports.* At the end of each payment year, the issuer must, in a form and manner specified by HHS, confirm to HHS 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.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 18. The authority citation for part 158 is revised to read as follows:

Authority: 42 U.S.C. 300gg-18.

■ 19. Section 158.110 is amended by revising paragraph (a) to read as follows:

§ 158.110 Reporting requirements related to premiums and expenditures.

(a) *General requirements.* For each MLR reporting year, an issuer must submit to the Secretary a report which complies with the requirements of this part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued. Reporting requirements of this part that apply to expenses incurred directly by the issuer also apply to expenses for functions outsourced to or services provided by other entities retained by the issuer.

* * * * *

■ 20. Section 158.140 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(1) * * *

(i)(A) For MLR reporting years before 2022, prescription drug rebates received by the issuer;

(B) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions received and retained by the issuer, and prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

* * * * *

■ 21. Section 158.150 is amended by revising paragraph (b)(2)(iv)(A)(5) to read as follows:

§ 158.150 Activities that improve health care quality.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(A) * * *

(5)(i) For MLR reporting years before 2021, actual rewards, incentives, bonuses, and reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims should be allowed as a quality improvement activity for the group market to the extent permitted by section 2705 of the PHS Act;

(ii) Beginning with the 2021 MLR reporting year, actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims, to the extent permitted by section 2705 of the PHS Act;

* * * * *

■ 22. Section 158.160 is amended by adding paragraph (b)(2)(vii) to read as follows:

§ 158.160 Other non-claims costs.

* * * * *

(b) * * *

(2) * * *

(vii) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

Dated: April 27, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 28, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020-10045 Filed 5-7-20; 4:15 pm]

BILLING CODE 4120-01-P