DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

[CMS–9916–P]

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: Proposed rule.

SUMMARY: This proposed 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 proposes changes related to essential health benefits and would provide states with additional flexibility in the operation and establishment of Exchanges. It includes proposed changes related to cost-sharing for prescription drugs; excepted benefit health reimbursement arrangements offered by non-Federal governmental plan sponsors; the medical loss ratio program; Exchange eligibility and enrollment; exemptions from the requirement to maintain coverage; quality rating information display standards for Exchanges; and other related topics. It also proposes to repeal regulations relating to the Early Retiree Reinsurance Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 2, 2020.

ADDRESSES: In commenting, please refer to file code CMS–9916–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9916–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9916–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Usree *Bandyopadhyay,* (410) 786–6650, Kiahana Brooks, (301) 492–5229, or Evonne Muoneke (301) 492–4402, for general information.

David Mlawsky, (410) 786–6851, for matters related to excepted benefit health reimbursement arrangements (HRAs).

Allison Yadsko, (410) 786–1740, Joshua Paul, (301) 492–4347, or Krutika Amin, (301) 492–5153, for matters related to risk adjustment.

Aaron Franz, (410) 786–8027, for matters related to federally-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees and sequestration.

Joshua Paul, (301) 492–4347, or Allison Yadsko, (410) 786–1740, for matters related to risk adjustment data validation (RADV).

Joshua Paul, (301) 492–4347, for matters related to the premium adjustment percentage.

Rebecca Zimmermann, (301) 492–4396, for matters related to value-based insurance plan design.

Becca Bucchieri, (301) 492–4341, for matters related to essential health benefit (EHB)-benchmark plans and defrayal of state-required benefits.

Jill Gotts, (202) 603–0480, for matters related to eligibility appeals.

Emily Ames, (301) 492–4246, for matters related to coverage effective dates and termination notices.

Marisa Beatley, (301) 492–4307, for matters related to employer-sponsored coverage verification and periodic data matching (PDM).

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

Kendra May, (301) 492–4477, for matters related to terminations.

Ken Buerger, (410) 786–1190, for matters related to cost-sharing requirements.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio (MLR) program.

Kevin Kendrick, (301) 492–4127, for matters related to the Early Retiree Reinsurance Program (ERRP).

Jenny Chen, (301) 492–5156, Shilpa Gogna, (301) 492–4257 or Nidhi Singh Shah, (301) 492–5110), for matters related to quality rating information display standards for Exchanges.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges,'' are entities established under the Patient Protection and Affordable Care Act [1] (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 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 proposed rule, we propose, within the limitations of current law, 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 proposed rule, we propose to amend some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These proposed changes are intended to provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs. The proposals would also provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability. In addition, we solicit comment 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. Finally, we discuss an alternative to the current requirement that Exchanges use random sampling as part of their methods for verifying eligibility for or enrollment in an eligible employer-sponsored plan that we are considering for future rulemaking. We also announce 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 propose recalibrated parameters for the HHS-operated risk adjustment methodology. To reduce issuer burden in participating in the risk adjustment program, we also propose changes intended to alleviate burden for small issuers associated with participating in risk adjustment data validation (RADV).

As we do every year in the HHS notice of benefit and payment parameters, we propose updated parameters applicable in the individual and small group markets. We propose the 2021 plan year user fee rates for issuers offering plans through the Exchanges using the Federal platform. We propose maintaining the Federal-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. Alternatively, we are considering and seek comment on reducing the FFE and SBE–FP user fee rates below 2020 plan year levels. We are also seeking information 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.

As we do every year, we also propose to update the maximum annual limitations on cost sharing for the 2021 benefit year, including those for 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 are 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 detailed options 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 propose new rules related to special enrollment periods. We propose to 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 propose to 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 also propose to shorten the time between the date a consumer enrolls in a plan through certain special enrollment periods and the effective date of that plan. We further propose to 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 propose 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

[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 proposed rule, we refer to the two statutes collectively as the ''Patient Protection and Affordable Care Act'' or ''PPACA''.

non-calendar year group health plan or individual health insurance coverage. We also propose to 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.

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

We also propose changes to the quality rating information display requirements for Exchanges. To continue providing flexibility for State Exchanges, we propose to codify 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 permissible 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. In order to minimize the potential for adverse selection in the Exchanges, 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 propose to allow issuers to include wellness incentives as quality improvement activities (QIA) in the individual market for MLR reporting and calculation purposes.

We propose 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 propose changes to the policy regarding how drug manufacturer coupons accrue towards the annual limitation on cost sharing. Specifically, we propose to revise § 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. We propose to interpret the definition of cost sharing not to include expenditures covered by drug manufacturer coupons.

We propose additional steps to ensure the proper execution of Federal requirements and to safeguard and conserve Federal funds. To protect against unnecessary overpayments of APTC funds, we propose to 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 propose 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 from MLR incurred claims not only when such rebates 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. We further propose 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 propose to repeal 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 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 AV requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. Section 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

[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.

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 information [4] 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-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. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(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

[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 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'').

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 Programs[6]

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

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

[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.

[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*.

average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

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

2. Program Integrity

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

3. Market Rules

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

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the 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 bulletin [9] 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 on April 25, 2019 (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 on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), and the April 17, 2018 **Federal Register** (83 FR 16930).

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

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 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.[10] 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.[11]

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, 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 proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 146, 149, 153, 155, 156 and 158.

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

The proposed changes to part 149 would delete the regulations related to the ERRP, which ended on January 1, 2014.

The proposed changes to 45 CFR part 153 would recalibrate 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. The proposals regarding part 153 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 propose several amendments to the definitions applicable to part 155. We discuss future changes to 45 CFR 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 Medicare dual enrollees 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 who are 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 propose to update 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 propose to update the user fee rates for the 2021 benefit year for all issuers participating on the Exchanges using the Federal platform. Further, a proposed change to 45 CFR part 156 would require QHP issuers to send to enrollees a termination notice for all termination events. We also propose to amend the

[10] 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 QRS star 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.*

[11] 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/QualityInitiativesGenInfo/Downloads/QRS-and-QHP-Enrollee-Survey-Technical-Guidance-for-2020-508.pdf.*

regulation addressing state selection of EHB-benchmark plans to require the reporting of state-required benefits. We also propose to offer QHP issuers the option to design value-based insurance plans that would empower consumers to receive high value services at lower cost. We propose to revise § 156.130(h) in its entirety to address how any direct support offered by drug manufacturers to enrollees for specific prescription drugs are treated with regard to accrual towards the annual limitation on cost sharing.

The proposed changes to 45 CFR part 158 would 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 or other entities providing pharmacy benefit management services to the issuers. The proposed 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 Proposed HHS Notice of Benefit and Payment Parameters for 2021

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

HHS proposes 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. Excepted benefit HRAs are a new type of excepted benefit the Departments recently established in the HRA rule.[12] The proposed 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 HRA rule, the Departments authorized a new form of HRA (the individual coverage HRA), and recognized certain HRAs as limited excepted benefits (the excepted benefit HRA), for plan years beginning on or after January 1, 2020. The individual coverage HRA and the excepted benefit HRA were designed to provide Americans with additional options to obtain quality, affordable health care by expanding the flexibility and use of HRAs. An entity may offer an individual coverage HRA subject to the HRA meeting the applicable conditions for individual coverage HRAs set forth in the HRA rule, including satisfying certain notice requirements. The notice must include a description of the terms of the individual coverage HRA, information regarding the PTC consequences of enrollment in the individual coverage HRA, and a statement about the ability to opt out of and waive future reimbursement from the individual coverage HRA, among other information.[13] The individual coverage HRA can be used to reimburse, among other medical care expenses, premiums for individual health insurance coverage.

Separately, under the HRA rule, benefits provided under an HRA or other account-based group health plan (other than a health flexible spending arrangement) will qualify as limited excepted benefits not subject to requirements under title XXVII of the PHS Act if they: (1) Are offered by a plan sponsor that also offers traditional group health plan coverage for the plan year to the participant; (2) are funded with amounts newly made available for each plan year that do not exceed $1,800, adjusted annually in a manner set forth in the HRA rule; (3) do not reimburse premiums for individual health insurance coverage, group health plan coverage (other than COBRA continuation coverage or other continuation coverage), or Medicare, except for coverage that consists solely of excepted benefits; and (4) are made available under the same terms to all similarly situated individuals, regardless of any health factor.

Commenters on the proposed HRA rule [14] suggested that the Departments provide certain notice requirements for excepted benefit HRAs. The commenters suggested that the required notice should be similar to the notice required for individual coverage HRAs as described above, or should, at a minimum, inform participants and beneficiaries of the annual dollar limit for benefits under the excepted benefit HRA, and participants' and beneficiaries' rights under the excepted benefit HRA.[15]

In the preamble to the HRA rule, the Departments noted that long-standing notice requirements under Part 1 of the 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 excepted benefit HRA plan sponsors 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.

HHS believes individuals offered excepted benefit HRAs by non-Federal governmental plan sponsors should also have access to clear information about their excepted benefit HRAs. Therefore, in the HRA rule, HHS announced its intent to propose notice requirements with respect to excepted benefit HRAs offered by non-Federal governmental plan sponsors in future notice and comment rulemaking. HHS indicated that it anticipated proposing that a non-Federal governmental plan excepted benefit HRA 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 plan, and a description or summary of the benefits consistent with the requirements of Department of Labor (DOL) summary plan description regulations at 29 CFR 2520.102–3(j)(2) and (3). Further, HHS indicated that, under its anticipated proposal, this notice would be required to be provided in a time and manner consistent with the requirements of DOL regulations at 29 CFR 2520.104b–2(a).[16]

In this proposed rule, HHS proposes to add a new paragraph (b)(3)(viii)(E) to § 146.145 that would require excepted benefit HRAs sponsored by non-Federal governmental entities to provide notice consistent with the discussion in the preamble to the HRA rule.[17] Specifically, under this proposal, 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

[12] 84 FR 28888 (June 20, 2019).

[13] Ibid at 28920–28924.

[14] 83 FR 54420 (October 29, 2018). This proposed rule was subsequently finalized, with some revisions in response to comments, by the final rule referenced in this preamble as the HRA rule.

[15] 84 FR 28888 at 28941.

[16] 84 FR 28888 at 28941.

[17] Ibid.

available under the excepted benefit HRA. This is generally consistent with the content requirements of DOL summary plan description regulations at 29 CFR 2520.102–3(j)(2) and (3), although the 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 propose 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.

We propose that this notice must be provided no later than 90 days after the employee becomes a participant in the excepted benefit HRA and annually thereafter. Under applicable rules at 45 CFR 144.103, ''participant'' is defined as having the meaning given the term under section 3(7) of the ERISA, which states, any employee or former employee of an employer, or any member or former member of an employee organization, who is or may become eligible to receive a benefit of any type from an employee benefit plan which covers employees of such employer or members of such organization, or whose beneficiaries may be eligible to receive any such benefit. Furthermore, 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 propose that the notice provided by non-Federal governmental plans must be provided on an annual basis 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 plan.

We propose this 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 seek comment on all aspects of this 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 solicit 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. For example, if, after the first year, this notice would be required only for plan years for which the terms of the excepted benefit HRA change from the previous plan year, sponsors of non-Federal governmental excepted benefit HRAs would incur lower costs to provide this notice to eligible participants. Therefore, we also seek 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 previous plan year, and if so, what type or magnitude of change should trigger such a subsequent notice. For example, should a change in the dollar amount of the excepted benefit HRA trigger such a notice, and if so, what magnitude of increase or decrease? Should a change in just one type of medical care expense that may or may not be reimbursed by the excepted benefit HRA trigger such a subsequent notice, or would a subsequent notice be required only if more than one type of reimbursable medical care expense is added or eliminated?

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

We propose 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. 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.

Repealing the ERRP regulations would reduce the volume of Federal regulations. Therefore, we propose to delete the regulations in part 149, and reserve part 149. We seek comment on this proposal.

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,[18] both the transitional reinsurance program and the permanent risk adjustment program are subject to the fiscal year 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 might be reinsurance payments in the 2020 fiscal year 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 fiscal year 2020 resources (that is, funds collected during the 2020 fiscal year).

HHS, in coordination with the OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99–177, enacted December 12, 1985), as amended, and the underlying authority for the reinsurance and risk adjustment program, the funds that are sequestered in fiscal year 2020 from the risk adjustment or reinsurance programs will become available for payment to issuers in fiscal year 2021 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

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

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.

We propose changes in this rule to recalibrate the risk adjustment models consistent with the methodology we finalized for the 2020 benefit year. For the 2021 benefit year, we propose to incorporate the 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 propose the risk adjustment user fee for the 2020 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 that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The current structure of these models is described in the 2020 Payment Notice.[19] 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 (RXCs) 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 propose 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,[20] we propose in this rule to no longer incorporate MarketScan® data in the recalibration process beginning with the 2021 benefit year. Rather, we propose for the 2021 benefit year and beyond to blend the 3 most recent years of available enrollee-level EDGE data. This approach would incorporate the most recent years' claims experience that is available without resulting in drastic year-to-year changes to risk scores, as the recalibration of the models for the applicable benefit year would maintain 2 years of EDGE data that were used in the previous years' models. It also would continue our efforts to recalibrate the risk adjustment models using actual data from issuers' individual and small group populations and complete the transition from the MarketScan® commercial database that merely approximates individual and small group (including merged) market populations. For the 2021 benefit year, we propose to use 2016, 2017, and 2018 enrollee-level EDGE data to recalibrate the risk adjustment models. We propose to maintain 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, unless changed through rulemaking.

We seek comment on 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. We also seek comment on 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.

Due to the timing of this proposed rule, we are unable to incorporate the 2018 benefit year enrollee-level EDGE data in the calculation of the proposed coefficients in this rule. Therefore, consistent with prior years' proposed payment notices (2017 and 2019), the coefficients listed below are 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 plan to use to recalibrate the 2021 risk adjustment models are reflected in the coefficients that we are publishing in this proposed rule, we believe that the draft coefficients listed below provide a reasonably close approximation of what could be anticipated from blending the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. If we finalize the proposed recalibration approach and are unable to incorporate the 2018 benefit year EDGE data in time to publish updated coefficients in the final rule, we will publish the final coefficients for the 2021 benefit year in guidance after the publication of the

[19] See 84 FR 17454 at 17463.

[20] 84 FR 17454 at 17464.

final rule, consistent with our approach in previous benefit years.[21]

(2) Updates to the Risk Adjustment Model Recalibration Hierarchical Condition Categories (HCCs)

We propose to incorporate the HCC changes identified below beginning with the 2021 benefit year risk adjustment models. The main purpose of these 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 propose to update the HHS–HCC clinical classification in the current 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 and small group markets.

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,[22] the HHS–HCC clinical classification has not been modified since it was implemented in the 2014 benefit year.

The HHS–HCC clinical classification, in place since 2014, was based on the International Classification of Diseases, 9th Edition, Clinical Modification (ICD–9–CM) diagnosis codes, an approved U.S. modification of the World Health Organization's classification system that was currently in use at the time. That system was subsequently replaced by the International Classification of Diseases, 10th Revision (ICD–10–PCS) and International Classification of Diseases, 10th Revision, Clinical Modification (a corresponding U.S. clinical modification) (ICD–10–CM). When ICD–10–CM was implemented in the U.S. on October 1, 2015, ICD–10 codes were cross-walked to ICD–9 codes and to the existing ICD–9-based HHS–HCC clinical classification.

In preparation for proposing these changes in this rulemaking, we released a paper on June 17, 2019 entitled ''Potential Updates to the HHS–HCCs for the HHS-operated Risk Adjustment Program'' (HHS–HCCs Update Paper).[23] 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 models to better incorporate coding changes made in the transition to 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,[24] 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–HCCs Update 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,[25] and that were used to develop the HCC classification system for the Medicare risk adjustment model.[26] 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.
- *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 propose to reclassify.

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.[27] We also conducted a series of clinical reviews to inform potential changes. Next, we reviewed the payment model and full classification

[21] 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).

[22] 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 into HCC 37_1—Chronic Viral Hepatits and HCC 37_2—Chronic Hepatitis, Other/Unspecified. See 81 FR 94058 at 94085 (December 22, 2016).

[23] 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.*

[24] 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.

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

[26] 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.*

[27] 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.

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.[28]

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 model—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 reclassification analysis, we propose to incorporate the changes presented in Table 1 to payment HCCs beginning with the 2021 benefit year risk adjustment models.

TABLE 1—SUMMARY OF PROPOSED PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES

Condition	Payment HCC proposed change	Summary of proposed payment HCC changes
Payment HCC Changes		
Substance Use Disorders	+3	• Add 2 new HCCs for alcohol use disorders and one new HCC for lower severity drug use disorders to risk adjust for a larger number of substance use diagnoses for all models.[29] • 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 for all 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 for all models.
Pregnancy	+3	• Add 3 (ongoing) pregnancy-without-delivery HCCs, leaving them ungrouped in the adult models (to reflect differences in costs by level of complications) and grouping them 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: Type 1	+1	• Add a diabetes type 1 additive HCC to the adult models to distinguish additional costs for diabetes type 1. • Remap hyperglycemia and hypoglycemia codes in the adult model from the ''chronic complications'' HCC to the ''without complication'' HCC based on clinical input.
Asthma	+1	• Split current asthma HCC into two severity-specific HCCs given new clinical distinctions for severity levels in the ICD–10 and to distinguish costs by severity for all models. • Continue to group asthma HCCs with chronic obstructive pulmonary disease HCC in adult model and leave the 3 HCCs ungrouped to distinguish costs in child models.
Fractures	−1, +1	• Delete an HCC (pathological fractures) to address a clinical distinction that may be inconsistently diagnosed/coded for all models. • Reconfigure an existing HCC (hip fractures) to better distinguish fracture codes by site for all models. • Add a new HCC (vertebral fractures) to better predict vertebral fractures, which may be indicative of chronic disease and frailty for all models.
Third Degree Burns and Major Skin Conditions.	+2	• Reconfigure and add 2 HCCs (extensive third degree burns; major skin burns or conditions) 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 for all models. • Impose an *a priori* constraint[30] between extensive third degree burns and severe head injury in child models due to small sample size.
Coma and Severe Head Injury.	+1	• Add a new severe head injury HCC (represents a condition with ongoing care costs; similar to the inclusion of other injury HCCs) in a hierarchy above the coma/brain compression for all models. • Impose an *a priori* constraint between extensive third degree burns and severe head injury in the child models due to small sample size.
Traumatic Amputations	+1	• Add a new HCC in a hierarchy with the current amputation status HCC and reconfigure codes between the new HCC and current amputation status HCC to better distinguish early treatment and complication costs from long-term costs for all models. • Leave HCCs ungrouped in the adult models; group them in the child model for coefficient stability purposes due to small sample size.
Narcolepsy and Cataplexy	+1	• 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	• 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	• 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	• 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 the models due to grouping). • Ungroup HCCs 29 and 30 in the adult models as they have adequate sample sizes and clinical and cost distinctions.

[28] To further clarify, in the HHS–HCCs Update 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.

[29] References to ''all models'' in Table 1 refers to the adult, child and infants models.

[30] 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.

TABLE 1—SUMMARY OF PROPOSED PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES—Continued

Condition	Payment HCC proposed change	Summary of proposed payment HCC changes
		• 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	• 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	• 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 in both adult and child models based on clinical input.
Mental Health	N/A	• Move delusional disorders/psychosis HCC above major depressive disorders/bipolar disorders HCC in the hierarchy and renumber the HCCs (that is, HCCs 88 and 89 switch positions) because the costs and diagnoses associated with the HCC are more aligned with HCC 87 (Schizophrenia) for all models. • Relabel HCCs to align with ICD–10 categorizations for all models.
Cerebral Palsy and Spina Bifida.	N/A	• Refine hierarchies to exclude paralysis HCCs for enrollees with cerebral palsy HCCs, as ICD–10 coding guidelines prohibit these conditions from coding together for all models. • Refine hierarchies to exclude hydrocephalus HCC for enrollees with spina bifida HCC for similar coding restriction purposes for all models.
Pancreatitis	N/A	• Reconfigure the acute pancreatitis HCC to move pancreatic disorders and intestinal malabsorption out of the acute pancreatitis HCC to differentiate higher cost conditions for all models. • 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 for all models.
Liver	N/A	• Reconfigure codes in liver HCCs to reflect clinical distinctions for all models. • 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 for all models.
Summary of the Adult Model Specific Changes		
Payment HCC change	+17	• Net change of 17 HCCs; 18 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Severe Illness Interactions	−1 (other model variable).	• 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	+12	• Net change of 12 HCCs; 13 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Transplant *A Priori* Constraints.	N/A	• Revise *a priori* constraints applied to the transplant HCCs to better distinguish costs while improving estimate stability due to small sample sizes and unconstrained HCC 129 Cystic Fibrosis from HCC 158 Lung Transplant Status/Complications due to the high associated drug costs and higher predicted costs.
Summary of the Infant Model Specific Changes		
Payment HCC change	+8	• Net change of 8; 9 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Categorical Model	N/A	• 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.

We propose to incorporate these changes into the risk adjustment coefficients beginning with the 2021 benefit year and they are reflected in the draft factors below.[31] Under the above-proposed HHS–HCC updates, we made one modification to the child model from the potential updates described in HHS–HCCs Update Paper. In the paper, we noted that we may re-examine the hierarchy violation constraints for non-transplant HCCs in the child model that affect the predicted costs of the transplant set. We explained that HCC 159 Cystic Fibrosis in the child model, 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 address this hierarchy violation, we propose in this rule to not impose a hierarchy in this case beginning with the 2021 benefit year coefficients in the child models and propose to remove a constraint for HCC 159 Cystic Fibrosis to allow it to have higher predicted costs than HCC 158 Lung Transplant Status/Complications.

We are proposing 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 at one time. Additionally, to assist commenters in reviewing the code level changes, we are providing 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 here at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html.*[32] While we recognize that the number of HHS–HCC changes proposed in this rule is significantly higher than in previous annual Payment Notice rulemakings, we do not expect to make significant HHS–HCC changes each year. We solicit comment on all of the proposed HHS–HCC updates.

For the 2020 benefit year adult models, we made a pricing adjustment for one RXC coefficient for Hepatitis C drugs.[33] 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

[31] As noted earlier, the factors displayed in this rulemaking reflect the equally weighted blended factors from the 2016 and 2017 enrollee-level EDGE data separately solved models, including all of the proposed HHS–HCC updates and the proposed constraints for the Hepatitis C RXC coefficient. If the recalibration policies are finalized as proposed, we would incorporate the 2018 enrollee-level EDGE data in the coefficients listed in the final rule or, if necessary, after publication of the final rule consistent with 45 CFR 153.320(b)(1)(i).

[32] The Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year includes 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 CMS includes as part of the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software.

[33] 84 FR 17454 at 17463 through 17466.

data.[34] For the 2021 benefit year model recalibration, we reassessed the Hepatitis C RXC to consider whether the 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 continue to believe that a pricing adjustment is needed for this RXC coefficient and are proposing to adjust the Hepatitis C RXC for the 2021 benefit year model recalibration. For the proposed RXC coefficients listed in Table 2 of this 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 propose 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. Applying an adjustment to the plan liability would 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.

In light of the recent recommendation by the U.S. Preventive Service Task Force to expand the use of pre-exposure prophylaxis (PrEP) as a preventive service that must be covered by applicable health plans for persons who are at high risk of HIV acquisition,[35] we also propose 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.[36] Currently, PrEP is not incorporated into RXC 1 (Anti-HIV) because PrEP does not indicate an HIV/AIDS diagnosis.[37] 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.[38] Although preventive services are incorporated in the simulation of plan 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 are reflected in the simulation of plan liability; preventive services are applied under relevant recommended conditions or groups. We propose 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 seek 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.

Given that we are proposing to no longer use the MarketScan® data to recalibrate the risk adjustment models beginning with the 2021 benefit year, 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 are not proposing 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. However, we intend to 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.

(3) Improving Risk Adjustment Model Predictions

In addition to the aforementioned updates to the HHS–HCCs, we are soliciting comment on different options to modify the risk adjustment models to improve model prediction for enrollees without HCCs or enrollees with low actual expenditures. In the 2018 Payment Notice, we stated that based on the commercial MarketScan® data, the HHS risk adjustment models slightly under-predict risk for low-cost enrollees and slightly over-predict risk for high-cost enrollees.[39] More precisely, the current 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 2018 Payment Notice, we also sought comments on ways to address these issues in response to feedback from stakeholders that HHS should adjust the risk adjustment models to address the under-prediction of risk for low cost enrollees and the over-prediction of risk for enrollees with higher expenditures, which affects the plan liability risk scores of plans that enroll more healthy individuals or plans that enroll more individuals with the most extreme chronic health conditions.[40] While we did not implement changes to address these issues, we indicated we would continue to explore different options to improve the models' predictive power for certain subgroups of enrollees, including analyses of these issues using enrollee-level EDGE data once available,

[34] Ibid.

[35] 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.*

[36] 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.*

[37] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf.*

[38] 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.*

[39] See 81 FR 61455 at 61472 through 61473. Also see 81 FR 94058 at 94082 through 94083.

[40] 81 FR 94058 at 94082 through 94083.

and consider changes for future benefit years.[41]

As detailed below, we are still evaluating the tradeoffs that would need to be made in model predictive power among subgroups of enrollees. We continue to believe that further evaluation is appropriate before pursuing these options; however, we also recognize that additional stakeholder comment is a critical aspect to this analysis. Therefore, in this rule, we outline and solicit comment on the different options that we continue to consider to improve the models' predictive ability for certain subgroups of enrollees in light of experience and currently available information.

As detailed in the 2018 Payment Notice,[42] we previously considered implementing a constrained regression approach, under which we would estimate the adult risk adjustment model using only the age-sex variables, and then, we would re-estimate the model using the full set of HCCs, while constraining the value of the age-sex coefficients to be the same as those from the first estimation. At the time, 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, upon further analysis, we also found that the mean expenditures of individual HCCs under this approach were under-predicted compared to the current adult models. In particular, the mean expenditures of extremely expensive enrollees are more under-predicted under this approach than in the current adult models.

Another option we previously evaluated was directly adjusting plan liability risk scores outside of the models for these subpopulations.[43] Specifically, we evaluated using a post-estimation adjustment to the current models' individual-level risk scores in order to correct for the patterns of over- and under-prediction. Under this approach, we would adjust individual-level plan liability risk scores by 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. These adjustments would be based on predictive ratios calculated from the models. This approach would estimate the models for all five metal levels, and within each metal level, predictive ratios for each decile of predicted expenditures would be calculated to generate a ''predicted'' predictive ratio based on metal level, predictive ratio, and risk score. In theory, this approach should have the advantages of retaining the current models. We noted that, while we believed modifications of this type could improve the model's performance along this specific dimension (deciles of predicted expenditures), there is a risk that such modifications could unintentionally worsen model performance along other dimensions on which the model currently performs well. One possible problem is that the scores are being adjusted by the average predictive ratio of the predicted expenditure level they are in, not their own over- or under-prediction.

We recently reassessed this adjustment option given the availability of the more recent enrollee-level EDGE data and the implementation of several updates beginning with the 2018 benefit year.[44] 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 results 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 adopt either of them. However, 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 are examining non-linear and count model specifications and whether these options could be used to improve the current adult models' predictive power. Our initial analysis of these options has shown that these alternatives can improve prediction in the adult models.

For the non-linear model, we have been 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:

$$\text{Plan liability} = \text{Current Model} + (\Sigma\beta_i HCC_i)^p$$

Where:

$\Sigma\beta_i HCC_i$ = the sum of payment HCCs weighted by their parameter estimates;

p = an exponential factor estimated by the model.

The non-linear term could be interpreted as a measure of overall disease burden for the enrollee in which having combinations of conditions can have a larger effect than the sum of the individual conditions. 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 allows 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 believe that adding a non-linear term to the models could be a reasonable approach to potentially improve the prediction of the models. However, the non-linear model may not improve the prediction for all subpopulations in the models.

Under the count model that we have been considering, we would add 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). We are considering using 1 to 8 or more payment HCCs based on reviewing the information on enrollees with HCCs in the 2017 benefit year enrollee-level EDGE data. We found that the population size of enrollees with a given count of HCCs begins to drop off around 8 HCCs per enrollee. In general, the count model that we are considering is similar to the recently finalized Medicare Advantage risk adjustment model incorporating payment HCC counts.[45] Even though the Medicare Advantage count model has variables that use more than 8 HCCs in its model, this option would be generally more consistent with other programs than the non-linear model, and has yielded

[41] Ibid.

[42] Ibid.

[43] Ibid.

[44] 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).

[45] Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 1, 2019. *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

similar results in model performance and improving 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.

In short, both the non-linear and count models could allow the incremental effect of payment HCCs on plan liability to vary with the total number of payment HCCs (or overall disease burden). Our recent analyses on the enrollee-level EDGE data suggest that the non-linear and count models may yield considerable gains in the adult models for predictive accuracy across several groups when compared to the current linear model.

To further assess these approaches, we have been testing the impact of the count and non-linear model specifications on subpopulations within the adult model using the silver metal tier level and examining the model fit using the R-squared of the models and predictive ratios for various subgroups. As part of our analysis, we have been assessing the models based on subpopulations that can be determined by the age-sex categories, the number of HCCs an enrollee has, the applicable enrollment duration and other relevant criteria.

Based on the initial testing of both the count and non-linear models' impact on the adult silver model, 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. Unlike the current model and the count model, the non-linear model does not over-predict for enrollees with higher costs. While both the count and non-linear models show promise in terms of improving the HHS risk adjustment models' predictive power, we are not proposing to adopt either of these options as part of the 2021 benefit year recalibration. We believe further evaluation is needed of the model performance before choosing to implement such an approach. For example, we would like to assess these options using additional data and applying the options to different metal levels beyond the silver metal level to consider whether the results on subpopulations persist across metal levels, and whether the adoption of one or more of these options would necessitate adjustments to other model specifications. We also have concerns about making these changes concurrent with the numerous changes to the HCCs being proposed in this rule for the adult, child and infant models for the 2021 benefit year. As such, we intend to test the model specifications with an additional year of data before considering these model changes for future years.

As noted above, we continue to evaluate all of these alternative modeling approaches while considering several important trade-offs in making improvements to risk prediction and providing consistency year-to-year for issuers in the HHS-operated risk adjustment program. Although we do not propose to incorporate any of these options in the 2021 benefit year risk adjustment model recalibration in this rule, we are generally soliciting comments on these options. We also solicit comments on the incorporation of one (or more) of these approaches as part of the 2022 benefit year risk adjustment model recalibration or for other future benefit years, whether one of these approaches is preferable to the other and why, and any considerations that should be made to implement either model and to analyze the resulting factors. For example, we are interested in comments on the model specifications of the count and non-linear variables described in this rule (such as whether the described 8 HCC variables should be used for the count model). While we do not believe that the count or non-linear models would impact incentives to code additional HCCs in comparison to the current model, we are also interested in comments about whether and what considerations should be made about count and non-linear models' impact on coding incentives.

In addition to considering the non-linear and count model approaches for future benefit years, we are also considering potential adjustments to the enrollment duration factors in the adult models, as well as assessing whether such factors should be incorporated into the child and infant models. In the past, we found that partial-year enrollment is more common in the individual and small group markets than in the MarketScan® data, which generally reflects the large group market, that we had been using to recalibrate the risk adjustment models in prior years. Using the 2016 and 2017 enrollee-level EDGE data that recently became available, we have investigated heterogeneity (variations) in the relationship between partial-year enrollment and predicted expenditures. We have explored heterogeneity according to the presence of certain diagnoses, market (individual or small group),[46] 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) does 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.[47] 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 believe 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.

For the child and infant models, we analyzed incorporating enrollment duration factors 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

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

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

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 are not proposing to add partial year factors to the child or infant models.

We are not proposing any changes to the current enrollment duration factors for the adult models at this time given the aforementioned data limitation in the extracted enrollee-level EDGE data and the numerous changes to the HCCs being proposed in this rule for the 2021 benefit year. As previously mentioned, we intend to review the enrollment duration factor assumptions seen in the 2016 and 2017 benefit year enrollee-level EDGE data before considering changes for future benefit years. Although we do not propose any changes to enrollment duration factors as part of this rulemaking, we generally solicit comments on these options and potential changes to the enrollment duration factors for future benefit years.

Finally, as we analyzed the count and non-linear models and the enrollment duration factors (including potential changes to such factors) and evaluated the interaction of such changes, we also found that enrollment duration factors may no longer be needed if a count or non-linear model specification is applied to the HHS risk adjustment adult models. We intend to continue to conduct analysis on enrollment duration factors and the interaction of such changes on other potential updates to the risk adjustment models, using 2018 benefit year enrollee-level EDGE data once available, and will solicit comments on any such proposed changes for future benefit years.

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

The factors resulting from the equally weighted blended factors from the 2016 and 2017 enrollee-level EDGE data separately solved models, including all of the proposed HCC changes detailed in the previous section and the proposed constraints for the Hepatitis C RXC coefficient, are shown in Tables 2 through 7. As stated above, we believe that the draft coefficients listed below provide a reasonably close approximation of what could be anticipated from blending the 2016, 2017 and 2018 benefit years' enrollee-level EDGE data. If we finalize the recalibration approach proposed in this rule, 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.[48] The adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the $1 million threshold.[49] Table 2 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, and enrollment duration coefficients.

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

TABLE 2—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Demographic Factors					
	Age 21–24, Male	0.128	0.099	0.062	0.027	0.024
	Age 25–29, Male	0.138	0.108	0.070	0.034	0.031
	Age 30–34, Male	0.166	0.130	0.085	0.042	0.038
	Age 35–39, Male	0.198	0.154	0.102	0.051	0.047
	Age 40–44, Male	0.235	0.186	0.128	0.070	0.065
	Age 45–49, Male	0.269	0.214	0.149	0.085	0.079
	Age 50–54, Male	0.346	0.282	0.204	0.127	0.120
	Age 55–59, Male	0.391	0.319	0.233	0.150	0.142
	Age 60–64, Male	0.437	0.355	0.261	0.167	0.159
	Age 21–24, Female	0.212	0.170	0.113	0.059	0.054
	Age 25–29, Female	0.239	0.193	0.130	0.071	0.065
	Age 30–34, Female	0.315	0.256	0.185	0.117	0.111
	Age 35–39, Female	0.386	0.317	0.237	0.160	0.154
	Age 40–44, Female	0.442	0.363	0.272	0.185	0.177
	Age 45–49, Female	0.453	0.369	0.272	0.177	0.168
	Age 50–54, Female	0.489	0.401	0.296	0.191	0.181
	Age 55–59, Female	0.465	0.377	0.272	0.166	0.156
	Age 60–64, Female	0.466	0.375	0.265	0.155	0.145
	Diagnosis Factors					
HCC001	HIV/AIDS	5.048	4.623	4.355	4.286	4.282
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	7.523	7.302	7.196	7.241	7.248
HCC003	Central Nervous System Infections, Except Viral Meningitis	6.357	6.266	6.212	6.226	6.228
HCC004	Viral or Unspecified Meningitis	5.200	4.965	4.831	4.739	4.732
HCC006	Opportunistic Infections	6.905	6.829	6.780	6.732	6.727
HCC008	Metastatic Cancer	23.310	22.744	22.402	22.419	22.421
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	13.030	12.613	12.358	12.314	12.310
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	6.063	5.794	5.613	5.525	5.516
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	4.278	4.012	3.832	3.736	3.727
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.860	2.667	2.529	2.439	2.431
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.248	1.108	0.988	0.858	0.846
HCC018	Pancreas Transplant Status	2.602	2.537	2.494	2.494	2.493
HCC019	Diabetes with Acute Complications	0.481	0.414	0.349	0.282	0.276

[48] See 45 CFR 153.320(b)(1)(i).

[49] As detailed below, we are not proposing changes to the high-cost risk pool parameters for the 2021 benefit year. Therefore, consistent with the policy finalized in the 2020 Payment Notice, we would maintain the $1 million threshold and 60 percent coinsurance rate for the 2021 benefit year. See 84 FR at 17466 through 17468.

TABLE 2—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC020	Diabetes with Chronic Complications	0.481	0.414	0.349	0.282	0.276
HCC021	Diabetes without Complication	0.481	0.414	0.349	0.282	0.276
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19–21	0.493	0.432	0.400	0.342	0.336
HCC023	Protein-Calorie Malnutrition	11.452	11.450	11.455	11.553	11.561
HCC026	Mucopolysaccharidosis	29.027	28.794	28.644	28.659	28.661
HCC027	Lipidoses and Glycogenosis	29.027	28.794	28.644	28.659	28.661
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	7.542	7.410	7.320	7.287	7.284
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.890	1.792	1.715	1.649	1.644
HCC034	Liver Transplant Status/Complications	10.612	10.532	10.481	10.478	10.475
HCC035_1	Acute Liver Failure/Disease, Including Neonatal Hepatitis	10.010	9.944	9.902	9.941	9.941
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	3.346	3.145	3.034	3.023	3.021
HCC036	Cirrhosis of Liver	1.189	1.066	0.984	0.917	0.910
HCC037_1	Chronic Viral Hepatitis C	0.967	0.852	0.775	0.707	0.701
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.967	0.852	0.775	0.707	0.701
HCC041	Intestine Transplant Status/Complications	37.750	37.652	37.589	37.563	37.564
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	9.512	9.264	9.117	9.131	9.133
HCC045	Intestinal Obstruction	5.721	5.459	5.315	5.286	5.284
HCC046	Chronic Pancreatitis	4.065	3.860	3.754	3.762	3.764
HCC047	Acute Pancreatitis	3.357	3.091	2.947	2.876	2.872
HCC048	Inflammatory Bowel Disease	2.466	2.283	2.148	2.037	2.026
HCC054	Necrotizing Fasciitis	11.372	11.264	11.191	11.262	11.266
HCC055	Bone/Joint/Muscle Infections/Necrosis	5.586	5.381	5.258	5.277	5.279
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	4.212	3.966	3.797	3.735	3.729
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.841	0.716	0.607	0.477	0.464
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.728	2.522	2.381	2.295	2.287
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.728	2.522	2.381	2.295	2.287
HCC063	Cleft Lip/Cleft Palate	2.077	1.912	1.798	1.715	1.709
HCC066	Hemophilia	70.505	70.072	69.794	69.809	69.810
HCC067	Myelodysplastic Syndromes and Myelofibrosis	14.381	14.246	14.162	14.150	14.149
HCC068	Aplastic Anemia	14.381	14.246	14.162	14.150	14.149
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	14.381	14.246	14.162	14.150	14.149
HCC070	Sickle Cell Anemia (Hb-SS)	2.797	2.644	2.532	2.451	2.444
HCC071	Beta Thalassemia Major	2.797	2.644	2.532	2.451	2.444
HCC073	Combined and Other Severe Immunodeficiencies	5.580	5.432	5.343	5.334	5.334
HCC074	Disorders of the Immune Mechanism	5.580	5.432	5.343	5.334	5.334
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.934	2.842	2.776	2.735	2.731
HCC081	Drug Use with Psychotic Complications	5.206	4.919	4.756	4.704	4.701
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications.	3.098	2.855	2.681	2.523	2.507
HCC083	Alcohol Use with Psychotic Complications	2.264	2.005	1.864	1.847	1.847
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications.	1.390	1.218	1.097	0.989	0.980
HCC085	Drug Use Disorder, Mild, Uncomplicated, Except Cannabis	0.993	0.836	0.704	0.549	0.534
HCC087	Schizophrenia	2.734	2.500	2.349	2.238	2.229
HCC088	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis.	2.724	2.500	2.349	2.238	2.229
HCC089	Major Depressive Disorder, Severe, and Bipolar Disorders	1.546	1.382	1.254	1.121	1.108
HCC090	Personality Disorders	1.178	1.055	0.940	0.802	0.788
HCC094	Anorexia/Bulimia Nervosa	2.787	2.612	2.484	2.399	2.391
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	7.260	7.189	7.142	7.098	7.092
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	1.413	1.319	1.243	1.175	1.168
HCC102	Autistic Disorder	1.235	1.125	1.010	0.877	0.864
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	1.178	1.055	0.940	0.802	0.788
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	12.545	12.385	12.284	12.256	12.253
HCC107	Quadriplegia	12.545	12.385	12.284	12.256	12.253
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	8.420	8.227	8.104	8.059	8.054
HCC109	Paraplegia	8.420	8.227	8.104	8.059	8.054
HCC110	Spinal Cord Disorders/Injuries	5.728	5.472	5.313	5.264	5.259
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	2.500	2.272	2.124	2.001	1.990
HCC112	Quadriplegic Cerebral Palsy	1.461	1.226	1.079	0.993	0.985
HCC113	Cerebral Palsy, Except Quadriplegic	0.766	0.661	0.577	0.485	0.476
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	1.640	1.497	1.399	1.326	1.319
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.608	5.480	5.403	5.388	5.386
HCC117	Muscular Dystrophy	1.871	1.723	1.615	1.502	1.490
HCC118	Multiple Sclerosis	4.312	4.071	3.906	3.814	3.805
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	1.871	1.723	1.615	1.502	1.490
HCC120	Seizure Disorders and Convulsions	1.176	1.031	0.925	0.824	0.815
HCC121	Hydrocephalus	8.731	8.600	8.508	8.481	8.479
HCC122	Coma, Brain Compression/Anoxic Damage	8.322	8.162	8.060	8.059	8.058
HCC123	Narcolepsy and Cataplexy	5.216	5.016	4.864	4.746	4.733
HCC125	Respirator Dependence/Tracheostomy Status	24.309	24.275	24.263	24.371	24.379
HCC126	Respiratory Arrest	7.162	6.991	6.911	7.005	7.016
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	7.162	6.991	6.911	7.005	7.016
HCC128	Heart Assistive Device/Artificial Heart	29.666	29.439	29.311	29.335	29.338
HCC129	Heart Transplant Status/Complications	29.666	29.439	29.311	29.335	29.338
HCC130	Heart Failure	2.668	2.560	2.494	2.480	2.479

TABLE 2—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC131	Acute Myocardial Infarction	7.022	6.720	6.551	6.599	6.605
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	5.250	4.924	4.756	4.734	4.734
HCC135	Heart Infection/Inflammation, Except Rheumatic	5.986	5.859	5.779	5.747	5.745
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.	2.826	2.703	2.606	2.538	2.532
HCC138	Major Congenital Heart/Circulatory Disorders	2.826	2.703	2.606	2.538	2.532
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.	2.826	2.703	2.606	2.538	2.532
HCC142	Specified Heart Arrhythmias	2.569	2.423	2.318	2.237	2.231
HCC145	Intracranial Hemorrhage	7.001	6.724	6.563	6.520	6.517
HCC146	Ischemic or Unspecified Stroke	1.669	1.516	1.434	1.391	1.388
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.891	2.700	2.577	2.495	2.488
HCC150	Hemiplegia/Hemiparesis	4.722	4.595	4.532	4.576	4.582
HCC151	Monoplegia, Other Paralytic Syndromes	3.044	2.909	2.822	2.767	2.762
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	9.241	9.131	9.079	9.187	9.198
HCC154	Vascular Disease with Complications	6.988	6.834	6.742	6.742	6.741
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	3.767	3.608	3.503	3.431	3.424
HCC158	Lung Transplant Status/Complications	24.105	23.953	23.866	23.912	23.916
HCC159	Cystic Fibrosis	8.916	8.553	8.315	8.257	8.253
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.887	0.771	0.669	0.560	0.550
HCC161_1	Severe Asthma	0.887	0.771	0.669	0.560	0.550
HCC161_2	Asthma, Except Severe	0.887	0.771	0.669	0.560	0.550
HCC162	Fibrosis of Lung and Other Lung Disorders	2.069	1.953	1.877	1.816	1.809
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.983	6.979	6.977	7.024	7.028
HCC174	Exudative Macular Degeneration	1.623	1.444	1.322	1.195	1.183
HCC183	Kidney Transplant Status/Complications	6.450	6.230	6.091	6.009	6.013
HCC184	End Stage Renal Disease	25.460	25.135	24.947	25.122	25.210
HCC187	Chronic Kidney Disease, Stage 5	1.310	1.251	1.219	1.234	1.242
HCC188	Chronic Kidney Disease, Severe (Stage 4)	1.310	1.251	1.219	1.234	1.242
HCC203	Ectopic and Molar Pregnancy	2.232	1.929	1.728	1.468	1.445
HCC204	Miscarriage with Complications	0.878	0.754	0.613	0.392	0.367
HCC205	Miscarriage with No or Minor Complications	0.878	0.754	0.613	0.392	0.367
HCC207	Pregnancy with Delivery with Major Complications	4.401	3.896	3.635	3.286	3.259
HCC208	Pregnancy with Delivery with Complications	4.401	3.896	3.635	3.286	3.259
HCC209	Pregnancy with Delivery with No or Minor Complications	3.125	2.749	2.526	2.092	2.046
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	1.343	1.158	0.962	0.699	0.672
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.854	0.730	0.560	0.356	0.337
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.356	0.297	0.195	0.105	0.097
HCC217	Chronic Ulcer of Skin, Except Pressure	2.067	1.946	1.874	1.848	1.846
HCC218	Extensive Third Degree Burns	19.316	18.987	18.771	18.723	18.719
HCC219	Major Skin Burn or Condition	2.976	2.833	2.729	2.663	2.657
HCC223	Severe Head Injury	17.344	17.207	17.106	17.069	17.064
HCC226	Hip and Pelvic Fractures	8.859	8.562	8.388	8.418	8.421
HCC228	Vertebral Fractures without Spinal Cord Injury	5.295	5.072	4.928	4.846	4.838
HCC234	Traumatic Amputations and Amputation Complications	5.657	5.468	5.362	5.374	5.377
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	27.223	27.219	27.217	27.250	27.253
HCC253	Artificial Openings for Feeding or Elimination	8.573	8.481	8.432	8.485	8.489
HCC254	Amputation Status, Upper Limb or Lower Limb	2.358	2.206	2.120	2.095	2.095
	Interaction Factors					
SEVERE × HCC006	Severe illness × Opportunistic Infections	6.705	6.924	7.064	7.208	7.220
SEVERE × HCC008	Severe illness × Metastatic Cancer	6.705	6.924	7.064	7.208	7.220
SEVERE × HCC009	Severe illness × Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	6.705	6.924	7.064	7.208	7.220
SEVERE × HCC010	Severe illness × Non-Hodgkin Lymphomas and Other Cancers and Tumors.	6.705	6.924	7.064	7.208	7.220
SEVERE × HCC115	Severe illness × Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	6.705	6.924	7.064	7.208	7.220
SEVERE × HCC135	Severe illness × Heart Infection/Inflammation, Except Rheumatic	6.705	6.924	7.064	7.208	7.220
SEVERE × HCC145	Severe illness × Intracranial Hemorrhage	6.705	6.924	7.064	7.208	7.220
SEVERE × _G06A	Severe illness × HCC group G06A (HCC 67 Myelodysplastic Syndromes and Myelofibrosis or HCC 68 Aplastic Anemia or HCC 69 Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn).	6.705	6.924	7.064	7.208	7.220
SEVERE × G08	Severe illness × HCC group G08 (HCC 73 Combined and Other Severe Immunodeficiencies or HCC 74 Disorders of the Immune Mechanism).	6.705	6.924	7.064	7.208	7.220
	Enrollment Duration Factors					
	1 month of enrollment	0.252	0.219	0.196	0.183	0.182
	2 months of enrollment	0.252	0.219	0.196	0.183	0.182
	3 months of enrollment	0.252	0.219	0.196	0.183	0.182
	4 months of enrollment	0.215	0.184	0.159	0.147	0.146
	5 months of enrollment	0.201	0.174	0.149	0.135	0.134
	6 months of enrollment	0.176	0.152	0.128	0.115	0.114
	7 months of enrollment	0.123	0.105	0.087	0.076	0.075
	8 months of enrollment	0.085	0.073	0.059	0.051	0.051
	9 months of enrollment	0.051	0.042	0.033	0.028	0.027
	10 months of enrollment	0.000	0.000	0.000	0.000	0.000
	11 months of enrollment	0.000	0.000	0.000	0.000	0.000

TABLE 2—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Prescription Drug Factors					
RXC 01	Anti-HIV Agents	7.913	7.213	6.737	6.388	6.360
RXC 02	Anti-Hepatitis C (HCV) Agents	10.016	9.334	8.948	9.021	9.034
RXC 03	Antiarrhythmics	0.127	0.116	0.114	0.073	0.058
RXC 04	Phosphate Binders	1.998	1.987	1.980	1.913	1.775
RXC 05	Inflammatory Bowel Disease Agents	1.688	1.537	1.409	1.222	1.202
RXC 06	Insulin	1.940	1.753	1.549	1.315	1.293
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.793	0.676	0.563	0.399	0.382
RXC 08	Multiple Sclerosis Agents	21.606	20.549	19.915	19.748	19.731
RXC 09	Immune Suppressants and Immunomodulators	13.848	13.192	12.820	12.893	12.902
RXC 10	Cystic Fibrosis Agents	18.151	17.703	17.461	17.511	17.519
RXC 01 × HCC001	Additional effect for enrollees with RXC 01 (Anti-HIV Agents) and HCC 001 (HIV/AIDS).	−2.152	−1.718	−1.385	−0.930	−0.891
RXC 02 × HCC037_1, 036, 035, 034.	Additional effect for enrollees with RXC 02 (Anti-Hepatitis C (HCV) Agents) and (HCC 037_1 (Chronic Viral Hepatitis C) or 036 (Cirrhosis of Liver) or 035 (End-Stage Liver Disease) or 034 (Liver Transplant Status/Complications)).	−0.412	−0.208	−0.082	0.034	0.040
RXC 03 × HCC142	Additional effect for enrollees with RxC 03 (Antiarrhythmics) and HCC 142 (Specified Heart Arrhythmias).	0.000	0.000	0.000	0.000	0.000
RXC 04 × HCC184, 183, 187, 188.	Additional effect for enrollees with RxC 04 (Phosphate Binders) and (HCC 184 (End Stage Renal Disease) or 183 (Kidney Transplant Status) or 187 (Chronic Kidney Disease, Stage 5) or 188 (Chronic Kidney Disease, Severe Stage 4)).	0.000	0.000	0.000	0.000	0.000
RXC 05 × HCC048, 041	Additional effect for enrollees with RxC 05 (Inflammatory Bowel Disease Agents) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	−0.676	−0.629	−0.565	−0.520	−0.515
RXC 06 × HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 06 (Insulin) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	0.049	0.038	0.129	0.208	0.214
RXC 07 × HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 07 (Anti-Diabetic Agents, Except Insulin and Metformin Only) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	−0.481	−0.414	−0.349	−0.282	−0.276
RXC 08 × HCC118	Additional effect for enrollees with RxC 08 (Multiple Sclerosis Agents) and HCC 118 (Multiple Sclerosis).	−2.347	−1.771	−1.399	−1.043	−1.007
RXC 09 × HCC056 or 057 and 048 or 041.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)) and (HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders) or 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders)).	1.001	1.149	1.262	1.390	1.402
RXC 09 × HCC056	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders).	−4.212	−3.966	−3.797	−3.735	−3.729
RXC 09 × HCC057	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders).	−0.841	−0.716	−0.607	−0.477	−0.464
RXC 09 × HCC048, 041	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	−1.791	−1.655	−1.583	−1.517	−1.511
RXC 10 × HCC159, 158	Additional effect for enrollees with RxC 10 (Cystic Fibrosis Agents) and (HCC 159 (Cystic Fibrosis) or 158 (Lung Transplant Status/Complications)).	43.951	44.137	44.226	44.340	44.347

TABLE 3—HHS HCCS IN THE SEVERITY ILLNESS INDICATOR VARIABLE

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

TABLE 4—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.217	0.175	0.126	0.082	0.078
Age 5–9, Male	0.159	0.125	0.084	0.052	0.049

TABLE 4—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Age 10–14, Male	0.187	0.152	0.106	0.073	0.070
Age 15–20, Male	0.229	0.186	0.133	0.087	0.083
Age 2–4, Female	0.164	0.130	0.091	0.060	0.057
Age 5–9, Female	0.106	0.077	0.044	0.020	0.017
Age 10–14, Female	0.175	0.141	0.100	0.069	0.067
Age 15–20, Female	0.251	0.199	0.134	0.077	0.072
Diagnosis Factors					
HIV/AIDS	4.963	4.448	4.125	3.974	3.961
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	13.606	13.374	13.257	13.250	13.252
Central Nervous System Infections, Except Viral Meningitis	8.979	8.793	8.685	8.692	8.692
Viral or Unspecified Meningitis	3.297	3.038	2.882	2.694	2.676
Opportunistic Infections	15.380	15.343	15.312	15.287	15.283
Metastatic Cancer	38.340	38.034	37.827	37.835	37.835
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.944	9.643	9.433	9.331	9.322
Non-Hodgkin Lymphomas and Other Cancers and Tumors	8.185	7.898	7.693	7.569	7.557
Colorectal, Breast (Age <50), Kidney, and Other Cancers	4.162	3.968	3.822	3.694	3.681
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	4.162	3.968	3.822	3.694	3.681
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.089	0.955	0.840	0.717	0.706
Pancreas Transplant Status	11.602	11.388	11.260	11.196	11.191
Diabetes with Acute Complications	2.923	2.541	2.309	1.978	1.949
Diabetes with Chronic Complications	2.923	2.541	2.309	1.978	1.949
Diabetes without Complication	2.923	2.541	2.309	1.978	1.949
Protein-Calorie Malnutrition	15.462	15.352	15.286	15.324	15.327
Mucopolysaccharidosis	40.368	40.041	39.835	39.821	39.820
Lipidoses and Glycogenosis	40.368	40.041	39.835	39.821	39.820
Congenital Metabolic Disorders, Not Elsewhere Classified	5.342	5.207	5.103	5.035	5.028
Amyloidosis, Porphyria, and Other Metabolic Disorders	5.342	5.207	5.103	5.035	5.028
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.403	6.133	5.947	5.901	5.897
Liver Transplant Status/Complications	11.602	11.388	11.260	11.196	11.191
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.602	11.388	11.260	11.196	11.191
Chronic Liver Failure/End-Stage Liver Disorders	11.602	11.388	11.260	11.196	11.191
Cirrhosis of Liver	3.872	3.780	3.730	3.705	3.707
Chronic Viral Hepatitis C	3.654	3.477	3.370	3.375	3.379
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.171	0.103	0.045	0.000	0.000
Intestine Transplant Status/Complications	18.843	18.775	18.746	18.763	18.763
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	13.335	13.022	12.831	12.820	12.821
Intestinal Obstruction	5.279	5.057	4.899	4.788	4.777
Chronic Pancreatitis	12.466	12.206	12.054	12.051	12.051
Acute Pancreatitis	7.967	7.708	7.549	7.452	7.443
Inflammatory Bowel Disease	8.630	8.166	7.866	7.739	7.727
Necrotizing Fasciitis	3.865	3.630	3.462	3.372	3.364
Bone/Joint/Muscle Infections/Necrosis	3.865	3.630	3.462	3.372	3.364
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.660	4.380	4.177	4.082	4.074
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.853	0.719	0.594	0.457	0.443
Osteogenesis Imperfecta and Other Osteodystrophies	1.303	1.185	1.085	1.002	0.994
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.303	1.185	1.085	1.002	0.994
Cleft Lip/Cleft Palate	1.305	1.118	0.981	0.846	0.834
Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2	0.000	0.000	0.000	0.000	0.000
Hemophilia	72.963	72.352	71.961	71.927	71.924
Myelodysplastic Syndromes and Myelofibrosis	15.864	15.660	15.531	15.503	15.502
Aplastic Anemia	15.864	15.660	15.531	15.503	15.502
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	15.864	15.660	15.531	15.503	15.502
Sickle Cell Anemia (Hb-SS)	6.184	5.903	5.700	5.560	5.547
Beta Thalassemia Major	6.184	5.903	5.700	5.560	5.547
Combined and Other Severe Immunodeficiencies	6.330	6.151	6.031	5.981	5.976
Disorders of the Immune Mechanism	6.330	6.151	6.031	5.981	5.976
Coagulation Defects and Other Specified Hematological Disorders	4.965	4.828	4.724	4.642	4.635
Drug Use with Psychotic Complications	3.275	3.036	2.876	2.745	2.734

TABLE 4—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	3.275	3.036	2.876	2.745	2.734
Alcohol Use with Psychotic Complications	0.831	0.688	0.565	0.410	0.396
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	0.831	0.688	0.565	0.410	0.396
Drug Use Disorder, Mild, Uncomplicated, Except Cannabis	0.831	0.688	0.565	0.410	0.396
Schizophrenia	5.241	4.864	4.620	4.470	4.455
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.493	3.209	3.007	2.832	2.817
Major Depressive Disorder, Severe, and Bipolar Disorders	2.952	2.706	2.515	2.341	2.325
Personality Disorders	0.497	0.396	0.283	0.145	0.131
Anorexia/Bulimia Nervosa	2.438	2.226	2.065	1.954	1.943
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	1.556	1.402	1.294	1.202	1.193
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.556	1.402	1.294	1.202	1.193
Autistic Disorder	2.952	2.706	2.515	2.341	2.325
Pervasive Developmental Disorders, Except Autistic Disorder	0.527	0.442	0.341	0.226	0.216
Traumatic Complete Lesion Cervical Spinal Cord	10.660	10.444	10.322	10.337	10.341
Quadriplegia	10.660	10.444	10.322	10.337	10.341
Traumatic Complete Lesion Dorsal Spinal Cord	7.948	7.672	7.503	7.436	7.428
Paraplegia	7.948	7.672	7.503	7.436	7.428
Spinal Cord Disorders/Injuries	4.052	3.825	3.665	3.547	3.536
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	25.035	24.747	24.542	24.466	24.460
Quadriplegic Cerebral Palsy	4.502	4.268	4.155	4.153	4.155
Cerebral Palsy, Except Quadriplegic	0.887	0.724	0.606	0.476	0.463
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	2.436	2.284	2.181	2.112	2.106
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	11.304	11.122	11.009	11.018	11.020
Muscular Dystrophy	3.484	3.273	3.131	3.013	3.004
Multiple Sclerosis	12.435	11.963	11.675	11.652	11.650
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.484	3.273	3.131	3.013	3.004
Seizure Disorders and Convulsions	2.304	2.137	1.992	1.844	1.830
Hydrocephalus	5.235	5.125	5.045	5.012	5.009
Coma, Brain Compression/Anoxic Damage	5.348	5.203	5.104	5.056	5.051
Narcolepsy and Cataplexy	4.262	4.066	3.904	3.739	3.720
Respirator Dependence/Tracheostomy Status	33.399	33.291	33.254	33.422	33.437
Respiratory Arrest	10.466	10.201	10.058	10.029	10.027
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	10.466	10.201	10.058	10.029	10.027
Heart Assistive Device/Artificial Heart	18.843	18.775	18.746	18.763	18.763
Heart Transplant Status/Complications	18.843	18.775	18.746	18.763	18.763
Heart Failure	6.428	6.307	6.223	6.181	6.177
Acute Myocardial Infarction	5.114	4.984	4.935	4.944	4.947
Unstable Angina and Other Acute Ischemic Heart Disease	2.526	2.378	2.302	2.284	2.288
Heart Infection/Inflammation, Except Rheumatic	13.717	13.595	13.518	13.514	13.513
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	4.066	3.895	3.736	3.623	3.612
Major Congenital Heart/Circulatory Disorders	1.226	1.120	0.994	0.876	0.866
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.831	0.735	0.632	0.543	0.536
Specified Heart Arrhythmias	3.957	3.782	3.644	3.563	3.556
Intracranial Hemorrhage	11.763	11.547	11.426	11.425	11.426
Ischemic or Unspecified Stroke	3.610	3.533	3.497	3.498	3.501
Cerebral Aneurysm and Arteriovenous Malformation	3.322	3.116	2.986	2.900	2.892
Hemiplegia/Hemiparesis	7.246	7.110	7.024	6.991	6.987
Monoplegia, Other Paralytic Syndromes	3.285	3.098	2.978	2.898	2.890
Atherosclerosis of the Extremities with Ulceration or Gangrene	14.234	13.963	13.796	13.739	13.735
Vascular Disease with Complications	10.519	10.396	10.319	10.348	10.349
Pulmonary Embolism and Deep Vein Thrombosis	17.678	17.551	17.486	17.500	17.501
Lung Transplant Status/Complications	18.843	18.775	18.746	18.763	18.763
Cystic Fibrosis	40.080	39.483	39.100	39.106	39.106
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	3.156	2.986	2.856	2.739	2.729
Severe Asthma	0.818	0.633	0.468	0.270	0.251
Asthma, Except Severe	0.354	0.289	0.200	0.113	0.106

TABLE 4—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Fibrosis of Lung and Other Lung Disorders	1.708	1.621	1.529	1.444	1.436
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.676	6.622	6.585	6.603	6.605
Exudative Macular Degeneration	0.000	0.000	0.000	0.000	0.000
Kidney Transplant Status/Complications	11.602	11.388	11.260	11.196	11.191
End Stage Renal Disease	41.286	41.057	40.934	41.046	41.057
Chronic Kidney Disease, Stage 5	5.961	5.857	5.771	5.679	5.670
Chronic Kidney Disease, Severe (Stage 4)	5.961	5.857	5.771	5.679	5.670
Ectopic and Molar Pregnancy	1.847	1.546	1.348	1.100	1.080
Miscarriage with Complications	0.834	0.700	0.534	0.292	0.266
Miscarriage with No or Minor Complications	0.834	0.700	0.534	0.292	0.266
Pregnancy with Delivery with Major Complications	3.796	3.315	3.047	2.628	2.585
Pregnancy with Delivery with Complications	3.796	3.315	3.047	2.628	2.585
Pregnancy with Delivery with No or Minor Complications	2.681	2.342	2.111	1.635	1.578
(Ongoing) Pregnancy without Delivery with Major Complications	0.403	0.313	0.179	0.035	0.028
(Ongoing) Pregnancy without Delivery with Complications	0.403	0.313	0.179	0.035	0.028
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.403	0.313	0.179	0.035	0.028
Chronic Ulcer of Skin, Except Pressure	2.956	2.861	2.771	2.695	2.690
Extensive Third Degree Burns	16.269	16.040	15.884	15.865	15.864
Major Skin Burn or Condition	2.467	2.297	2.168	2.059	2.050
Severe Head Injury	16.269	16.040	15.884	15.865	15.864
Hip and Pelvic Fractures	4.925	4.669	4.475	4.362	4.354
Vertebral Fractures without Spinal Cord Injury	4.052	3.820	3.642	3.495	3.480
Traumatic Amputations and Amputation Complications	5.553	5.291	5.118	4.987	4.971
Stem Cell, Including Bone Marrow, Transplant Status/ Complications	18.843	18.775	18.746	18.763	18.763
Artificial Openings for Feeding or Elimination	11.570	11.418	11.359	11.471	11.484
Amputation Status, Upper Limb or Lower Limb	5.553	5.291	5.118	4.987	4.971

TABLE 5—PROPOSED INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2021 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	225.321	223.595	222.465	222.451	222.455
Extremely Immature * Severity Level 4	144.819	142.871	141.573	141.365	141.352
Extremely Immature * Severity Level 3	33.455	32.014	31.032	30.738	30.717
Extremely Immature * Severity Level 2	33.455	32.014	31.032	30.738	30.717
Extremely Immature * Severity Level 1 (Lowest)	33.455	32.014	31.032	30.738	30.717
Immature *Severity Level 5 (Highest)	142.379	140.578	139.388	139.305	139.299
Immature *Severity Level 4	71.986	70.220	69.038	68.884	68.870
Immature *Severity Level 3	33.455	32.014	31.032	30.738	30.717
Immature *Severity Level 2	25.570	24.161	23.190	22.827	22.795
Immature *Severity Level 1 (Lowest)	25.570	24.161	23.190	22.827	22.795
Premature/Multiples * Severity Level 5 (Highest)	110.794	109.215	108.168	108.011	107.996
Premature/Multiples * Severity Level 4	29.484	27.938	26.919	26.632	26.612
Premature/Multiples * Severity Level 3	14.338	13.201	12.389	11.819	11.768
Premature/Multiples * Severity Level 2	8.284	7.501	6.838	6.107	6.031
Premature/Multiples * Severity Level 1 (Lowest)	5.769	5.196	4.607	4.019	3.967
Term *Severity Level 5 (Highest)	86.802	85.471	84.564	84.347	84.329
Term *Severity Level 4	17.042	15.936	15.163	14.630	14.588
Term *Severity Level 3	6.318	5.730	5.154	4.524	4.466
Term *Severity Level 2	3.559	3.136	2.604	1.944	1.884
Term *Severity Level 1 (Lowest)	1.698	1.477	1.054	0.712	0.691
Age1 *Severity Level 5 (Highest)	65.628	64.812	64.248	64.124	64.114
Age1 *Severity Level 4	12.979	12.412	12.003	11.748	11.726
Age1 *Severity Level 3	3.335	3.059	2.809	2.602	2.585
Age1 *Severity Level 2	2.054	1.841	1.620	1.396	1.376
Age1 *Severity Level 1 (Lowest)	0.545	0.501	0.447	0.404	0.400
Age 0 Male	0.645	0.597	0.560	0.489	0.481
Age 1 Male	0.115	0.099	0.083	0.062	0.060

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/description
Extremely Immature	Extremely Immature Newborns, Birth weight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750–999 Grams.

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES—Continued

Maturity category	HCC/description
Immature	Premature Newborns, Including Birth weight 1000–1499 Grams.
Immature	Premature Newborns, Including Birth weight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birth weight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight.
Age 1	All age 1 infants.

TABLE 7—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC/description
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant Status/Complications.
Severity Level 5	Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status/Complications.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 4	Chronic Liver Failure/End-Stage Liver Disorders.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age <50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Combined and Other Severe Immunodeficiencies.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Drug Use with Psychotic Complications.

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

Severity category	HCC/description
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications.
Severity Level 3	Alcohol Use with Psychotic Complications.
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications.
Severity Level 3	Drug Use Disorder, Mild, Uncomplicated, Except Cannabis.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Extensive Third Degree Burns.
Severity Level 3	Severe Head Injury.
Severity Level 3	Hip and Pelvic Fractures.
Severity Level 3	Vertebral Fractures without Spinal Cord Injury.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Acute Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Severe Asthma.
Severity Level 2	Fibrosis of Lung and Other Lung Disorders.
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 2	Major Skin Burn or Condition.
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C.
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C.
Severity Level 1	Beta Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma, Except Severe.
Severity Level 1	Traumatic Amputations and Amputation Complications.
Severity Level 1	Amputation Status, Upper Limb or Lower Limb.

(5) Cost-Sharing Reduction Adjustments

We propose 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 are proposing to maintain the CSR factors

finalized in the 2019 and 2020 Payment Notices.[50] See Table 8.

Consistent with the approach finalized in the 2017 Payment Notice,[51] 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, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent.

We seek comment on these proposals.

TABLE 8—COST-SHARING REDUCTION ADJUSTMENT

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

(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.[52] 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 this proposed rule, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 9. If the proposed 2021 benefit year model recalibration data is finalized, we intend 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.

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

	R-Squared statistic	
Models	2016 enrollee-level EDGE data	2017 enrollee-level EDGE data
Platinum Adult	0.4256	0.4210
Gold Adult	0.4198	0.4148
Silver Adult	0.4154	0.4101
Bronze Adult	0.4123	0.4068
Catastrophic Adult	0.4119	0.4064
Platinum Child	0.3212	0.3382
Gold Child	0.3166	0.3336
Silver Child	0.3129	0.3299
Bronze Child	0.3095	0.3267
Catastrophic Child	0.3091	0.3263
Platinum Infant	0.3283	0.3303
Gold Infant	0.3245	0.3263
Silver Infant	0.3218	0.3235
Bronze Infant	0.3203	0.3220
Catastrophic Infant	0.3201	0.3218

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

We are proposing to continue to use the HHS state payment transfer formula that was finalized in the 2020 Payment Notice.[53] 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 believe it is useful to republish the formula in its entirety in this proposed rule. Additionally, we are republishing the description of the administrative cost reduction to the statewide average premium and high-cost risk pool factors, although these factors and terms also remain unchanged in this proposed rule.[54]

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.[55] 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,[56] 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.[57]

Risk adjustment transfers (total payments and charges, including high-cost risk pool payments and charges) are calculated after issuers have completed their risk adjustment EDGE data submissions for the applicable benefit year. Transfers (payments and charges) under the state payment transfer formula are calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. The state payment transfer calculation that is part of the HHS risk

[50] See 83 FR 16930 at 16953 and 84 FR 17454 at 17478 through 17479.

[51] See 81 FR 12203 at 12228.

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

[53] 84 FR 17454 at 17480 and 17485.

[54] Ibid.

[55] 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.

[56] 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).

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

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 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.[58] This resulting PMPM plan payment or charge is multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the state. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

We are maintaining the 14 percent administrative cost reduction to the statewide average premium for the 2021 benefit year and are not proposing to modify the adjustment at this time.[59]

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, [60] we intend to maintain the high-cost risk pool parameters with a threshold of $1 million and a coinsurance rate of 60 percent for benefit years 2020 and onward, unless amended through notice-and-comment rulemaking. We are not proposing any changes to the high-cost risk pool parameters as part of this rulemaking, so would maintain the threshold of $1 million and coinsurance rate of 60 percent 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:

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

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.

(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.[61]

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 HHS FOIA regulations at 45 CFR 5.31(d), HHS will make available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence.[62]

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

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

[59] See 84 FR 17454 at 17486 for a visual illustration of the equation for this adjustment.

[60] 84 FR 17454 at 17466 through 17468.

[61] 2019 Payment Notice Final Rule, 83 FR 16930 (April 17, 2018) and 45 CFR 153.320(d)(3).

[62] See 45 CFR 153.320(d)(3).

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 seek 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.*

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 be operating 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. 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.

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

In the 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 PMPM based on our estimated contract costs for risk adjustment operations and estimated billable member months for individuals enrolled in risk adjustment covered plans. For the 2021 benefit year, we propose to use the same methodology to estimate our administrative expenses to operate the program. These costs cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment program activities. To calculate the user fee, we divided HHS's projected total costs for administering the risk adjustment programs on behalf of states by the expected number of billable member months in risk adjustment covered plans in states where the HHS-operated risk adjustment program will apply in the 2021 benefit year.

We estimate 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. The risk adjustment user fee costs for the 2021 benefit year are expected to remain steady from the prior 2020 benefit year estimates. However, we project a small decline in billable member months in the individual and small group markets overall in the 2021 benefit year based on the declines observed in the 2018 benefit year. We seek comment on the proposed risk adjustment user fee for the 2021 benefit year.

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 HHS 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. Set forth below are proposed amendments and clarifications to the RADV program that stem from issuer feedback and HHS's examination of results from during the first 2 pilot years and first transfer adjustment year of the program. None of the policy options discussed in the ''HHS Risk Adjustment Data Validation (HHS–RADV) White Paper'',[63] published on December 6th, 2019, preclude or supersede the proposals in this proposed rule.

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

Beginning with the 2019 benefit year RADV, we propose to amend the outlier identification process when an issuer has fewer HCCs within an HCC group than are necessary to determine statistical significance. Specifically, we propose not to consider as an outlier any issuer's failure rate for an HCC group in which that issuer has fewer than 30 HCCs recorded on the issuer's EDGE server. Under this proposed approach, an issuer with fewer than 30 HCCs recorded on its EDGE server in an HCC group would have its data included in the calculation of the overall national metrics, but 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. Such an issuer could still be considered an outlier, and have its risk score adjusted, in another HCC group in which it had at least 30 HCCs recorded.

In the 2019 Payment Notice,[64] to avoid adjusting all issuers' risk

[63] See *https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.*

[64] 83 FR 16930.

adjustment transfers for expected variation and error, we finalized a proposal to evaluate material statistical deviation in data validation failure rates beginning with 2017 benefit year RADV. 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.[65]

Consistent with the methodology finalized in the 2019 Payment Notice, for RADV for 2017 and 2018 benefit years, we currently 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 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, which prevents small sample sizes for an HCC group for any issuer.

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:

$$\mu^*(GFR^G) = 1 - \frac{\sum Freq\_IVA_i^G}{\sum Freq\_EDGE_i^G}$$

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

Where:

μ(*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 = μ(*GFR*^{G}) − *sigma_cutoff* * *Sd*(*GFR*^{G})

UB^G = μ(*GFR*^{G}) + *sigma_cutoff* * *Sd*(*GFR*^{G})

Where:

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

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

When an issuer's HCC group failure rate is an outlier, we 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 μ(*GFR*^{G} calculated as:

If *GFR*$_i^G$ > *UB*^{G} or *GFR*$_i^G$ < *LB*^{G}:

Then *Flag*$_i^G$ = ''*outlier*'' and *Adjustment*$_i^G$ = *GFR*$_i^G$ − μ(*GFR*^{G})

If *GFR*$_i^G$ ≤ *UB*^{G} and *GFR*$_i^G$ ≥ *LB*^{G}:

Then *Flag*$_i^G$ = ''*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

[65] 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.

for each issuer based on the sums of the $Adjustment_i^G$.[66]

Although the failure rate and error estimation methodology described above are 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,[67] 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, at the targeted precision and confidence levels, whether an issuer is an outlier—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 theorems[68] state that, as sample sizes increase, the 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 a threshold of 30 HCCs per sample of enrollees below which the implied alpha of our statistical tests for outliers was higher than 5 percent. 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.[69]

Based on these findings, beginning with 2019 benefit year RADV, we propose to not consider as an outlier any issuer's failure rate for an HCC group in which that issuer has fewer than 30 HCCs. Such an issuer's data would 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. In addition, this issuer may be considered an outlier in other HCC groups in which it has 30 or more HCCs. Under this proposal, the adjustment amount for outliers will continue to be the distance between issuer *i*'s Group Failure Rate GFR_i^G and the weighted mean $\mu(GFR^G)$, now calculated as:

If $GFR_i^G > UB^G$ or $GFR_i^G < LB^G$,
And if $Freq\_EDGE_i^G \geq 30$:
Then $Flag_i^G =$ ''*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 $Freq\_EDGE_i^G$:
Then $Flag_i^G =$ ''*not outlier*'' and
$Adjustment_i^G = 0$

We are committed to monitoring and improving the RADV methodology as we gain experience with years for which we make transfer adjustments under the program, and believe that this proposed change will improve the precision and reliability of RADV results, while mitigating the burden on smaller issuers. We may explore additional methodological changes for future benefit years.

We solicit comments on this proposal.

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

We propose 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 pilot for prescription drugs. This proposal is intended to give HHS and issuers more time and experience with the prescription drug data validation process before those results would be used to adjust risk scores and transfers. The proposed second pilot year is consistent with the two pilot years provided for the 2015 and 2016 benefit years of the HHS RADV program. This proposal is also responsive to issuer concerns that were previously expressed in comments to the 2020 Payment Notice.[70]

In the 2020 Payment Notice,[71] 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 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. Through continued analysis of this issue after publication of the 2020 Payment Notice, we have recognized 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, after further consideration, we are proposing a second pilot year (2019 benefit year) for RXC validation.

We solicit comments on this proposal.

[66] 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.*

[67] 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.

[68] In other words, the Central Limit Theorem (CLT). For background regarding the CLT, see Ivo D. Dinov, Nicolas Christou, and Juana Sanchez. ''Central limit theorem: New SOCR applet and demonstration activity.'' Journal of Statistics Education 16, no. 2 (2008). DOI: 10.1080/10691898.2008.11889560.

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

[70] 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.*

[71] 84 FR 17454 at 17498 through 17503.

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

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 applies. Specifically, Exchanges must select a statistically significant random sample of applicants and meet the requirements of § 155.320(d)(4)(i). For benefit years 2016 through 2019, Exchanges also could use an alternative process approved by HHS. 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 sample enrollees have been determined by HHS to have received APTC/CSRs inappropriately. 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 now believes that this methodology may not be the best approach for all Exchanges to assess the associated risk for inappropriate payment of APTC/CSRs. As such, HHS is currently conducting a study to (1) determine the unique characteristics of the population with offers of employer-sponsored coverage that meets minimum value and affordability standards, (2) compare premium and out-of-pocket costs for consumers enrolled in affordable employer-sponsored coverage to Exchange coverage, and (3) identify the incentives, if any, that drive consumers to enroll in Exchange coverage rather than coverage offered through their current employer. The results of this study, which HHS expects to be finalized in early 2020, will inform the risk assessment 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 encourages 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 will not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4) for plan years 2020 and 2021. HHS will exercise such discretion in anticipation of receiving the results of the employer verification study described above and of the future changes discussed earlier in this preamble.

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)

In accordance with § 155.330(d), Exchanges must periodically examine available data sources 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 Basic Health Program (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 checks known as 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 periodic checks that the consumer has become eligible for or enrolled in other MEC. This consumer authorization to provide written consent 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).

We further note that for plan year 2019, 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 CMS 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, 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 expect 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 are proposing 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 (e)(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 believe that this 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 believe these 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 believe this 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 seek comment on this proposal.

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 may have become deceased during a plan year and subsequently terminate QHP coverage after following the process outlined at § 155.330(e)(2)(i) and following a redetermination of eligibility in accordance with § 155.330(e)(1).

In late 2019, Exchanges using the Federal platform will conduct periodic checks for enrollees who are enrolled in QHP coverage and may have become deceased during plan year 2019. Additionally, the Exchange will follow the termination process outlined at § 155.430(d)(7) that requires the Exchange to terminate QHP coverage retroactively to the date of death when the Exchange initiates a termination due to the death of an enrollee during a plan year. As such, we are proposing to further amend § 155.330(e)(2)(i)(D) by adding new language that clarifies when the Exchange identifies deceased enrollees via PDM, specifically for enrollees who do not respond or contest the updated information within the 30-day period specified in paragraph (e)(2)(i)(B), the Exchange will follow the process outlined in § 155.430(d)(7) and terminate coverage retroactively to the date of death, without a need to redetermine the eligibility of the deceased enrollee. We believe that these changes clarify the Exchange's operations when conducting periodic checks for deceased enrollees as part of PDM and would serve to 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 seek comment on this proposal.

3. Automatic Re-Enrollment Process

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 noted that enrollees in plans offered through Exchanges using the Federal platform can take action to re-enroll in their current plan, can take action to select a new plan, or can take no action and be 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 program's inception, Exchanges using the Federal platform have maintained an automatic re-enrollment process which generally continues enrollment for current enrollees who do not notify the Exchange of eligibility changes or take action to actively select the same or 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.

We continue to believe that while allowing auto-re-enrollment was designed to be consistent with broader industry practices, this market is different because most current enrollees receive significant government subsidies, making them potentially less sensitive to premiums and premium changes.

The proposed 2020 Payment Notice sought comment on automatic re-enrollment processes and capabilities, as well as additional policies or program measures that would reduce eligibility errors and potential government misspending for potential action in future rulemaking applicable not sooner than plan year 2021. 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 automatic re-enrollment processes. Supporters cited benefits such as the stabilization of the risk pool due to the retention of lower-risk enrollees who are least likely to actively re-enroll, the increased efficiencies and reduced administrative costs for issuers, the reduction of the numbers of uninsured, and lower premiums. Commenters stated that existing processes, such as eligibility redeterminations, electronic and document-based verification of eligibility information, PDM, and PTC 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. To that end, we remain concerned 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 believe 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.

As such, we solicit 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. This would ensure that any enrollee in this situation would need to return to the Exchange and obtain an updated eligibility determination prior to having APTC paid on his or her behalf for the upcoming year. We also request comments on a variation on this approach that we are considering finalizing in a final rule, where APTC for this population would be reduced to a level that would result in an enrollee premium that is greater than zero dollars, but not eliminated entirely. This variation would be designed to ensure a consumer's active involvement in re-enrollment, because any enrollment in a plan with an enrollee premium that is greater than zero would require the enrollee to take an action by making the premium payment to effectuate or maintain coverage, or else face eventual termination of coverage for non-payment. We would also appreciate commenters' perspectives on whether there are other approaches that could help limit risk in connection with automatic re-enrollment into plans with APTC that cover the entire plan premium. 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 application 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 note that under current regulations at § 155.335, each Exchange has some flexibility to define its own annual redetermination procedures. We solicit comment on whether the approaches discussed above should be adopted only for Exchanges using the Federal platform, or whether they should also be required 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 QHP coverage through an FFE during the 2020 plan year 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 coverage in a QHP for the 2021 plan year.[72] We believe the current auto-reenrollment process under § 155.335(j) (that was in place during the 2020 open enrollment period and prior years) aligns with this requirement.

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

For a 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 this proposed rule.

5. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for Cost-Sharing Reductions

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 addressed concerns that allowing individuals to enroll in coverage through a special enrollment period without electronic or document-based verification 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 based on ongoing health needs during the coverage year, negatively affecting 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.[73]

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,[74] 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 (d)(6)(i) or (ii) of this section and are not enrolled in a silver-level QHP, the Exchange must allow them to change to a silver-level QHP if they elect to change their QHP enrollment so that they may access CSRs they are eligible for.

However, there is 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) 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) because § 155.420(a)(4)(ii) does not include them and the provision at § 155.420(a)(4)(iii) that excepts the special enrollment period triggering events at § 155.420(d)(6)(i) and (ii) from this limitation only applies to individuals becoming newly eligible for CSRs, not those becoming newly ineligible for CSRs. 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 HHS Navigators and other enrollment assisters, as well as from agents and brokers, based on their experiences with consumers who, upon losing eligibility for CSRs, are unable to afford cost sharing for their current silver-level QHP and therefore wish to change to a lower-cost QHP in order to maintain their coverage.

Therefore, we propose 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 propose 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). This proposal may help impacted enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of a potentially significant change to their out of pocket costs. For example, an enrollee impacted 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. HHS requests comment on this proposal. 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

[72] Further Consolidated Appropriations Act, 2020, Division N, title I, subtitle F, section 608 (Pub. L. 116–94: December 20, 2019, enacting H.R. 1865).

[73] These limitations do not apply to enrollees who qualify for certain types of special enrollment period, 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 proposed rule.

[74] 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).

off-Exchange, he or she is not limited to any specific metal level(s) of coverage.

We seek comments on these proposals.

b. Special Enrollment Period Limitations for Enrollees Who Are Dependents

As discussed in the preceding section of this preamble, per § 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.[75] 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, or, 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.[76] 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. The current rules do not explicitly 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 rules do not currently 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. In fact, 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 whether the new enrollee is a dependent.[77]

Therefore, we are proposing to apply the same limitations to dependents who are currently enrolled in Exchange coverage that applies to current, non-dependent Exchange enrollees by adding 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.

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, 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) establish that § 155.420(a)(4) does not apply off-Exchange. Therefore, the existing and proposed requirements and restrictions of that section, including the proposed requirements that would require an issuer to newly enroll a non-dependent household member(s) who qualifies for a special enrollment period, with currently enrolled dependents, and the plan category limitations associated with that requirement, 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.

We seek comments on these proposals.

c. Special Enrollment Period Prospective Coverage Effective Dates

Under regular special enrollment period effective date rules at § 155.420(b)(1), the Exchange must 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 must 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 these 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, these rules apply

[75] 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).

[76] 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.

[77] 82 FR at 10986.

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 harm to the individual per the trigger 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, all issuers 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.[78] 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, as a program integrity measure, we believe any changes in enrollment related to changes in eligibility for coverage through the Exchange or for insurance affordability programs should be implemented as soon as practicably possible. 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. Therefore, we propose 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 propose to amend § 155.420(b)(3) for improved clarity and to specify how Exchanges using the Federal platform would implement this proposal.

This proposal would permit Exchanges, including those using the Federal platform, and issuers to more rapidly implement changes in QHP enrollment, particularly those related to changes in financial assistance eligibility, and would standardize prospective special enrollment period effective dates across the Exchanges using the Federal platform. It would also help reduce consumer confusion regarding different effective date rules and minimize gaps in coverage. For example, under current rules, a consumer in off-Exchange coverage who is eligible for a special enrollment period because she gains access to new QHPs as a result of a permanent move under § 155.420(d)(7) would be subject to regular effective date rules under § 155.420(b)(1) (because the Exchanges using the Federal platform have not adopted the option under § 155.420(c)(2) to provide advanced availability of the special enrollment period under § 155.420(d)(7)). This means that if she moved out of her current plan's service area on May 10 and selected a QHP on May 16, the FFE would set an effective date for her new coverage of July 1; she could therefore be with limited coverage in her new service area—or no coverage, if her current issuer terminates her coverage based on her moving outside the issuer's service area—for almost 2 months. Instead, under our proposal to modify prospective special enrollment period effective dates so that coverage is effective the first of the month following plan selection, this enrollee would have coverage beginning June 1, minimizing any unintended gap in coverage.

This proposal would also allow State Exchanges the flexibility to retain current special enrollment period regular effective date rules or to adopt the approach that would be taken in the Exchanges using the Federal platform. State Exchanges already have flexibility under § 155.420(b)(3) to effectuate coverage in a shorter timeframe if their issuers agree. Several State Exchanges have already transitioned to faster than regular effective date rules for special enrollment periods. Under our proposed changes, State Exchanges could 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). This proposal would continue to provide the applicable state authority with flexibility regarding the options for effective dates under current rules for off-Exchange coverage.

We note that many special enrollment periods already have effective date rules that provide Exchanges and/or qualified individuals or enrollees with discretion regarding effective dates, regardless of issuer concurrence. Under § 155.420(b)(2)(i), (iv), and (v), Exchanges and/or qualified individuals or enrollees have the option to apply regular effective date rules or provide an effective date on the first of the month following plan selection for special enrollment periods provided under § 155.420(d)(1) and (3), (d)(6)(iii) and (iv), and (d)(7), and certain triggering events under (d)(2). Under § 155.420(b)(2)(iii), Exchanges have discretion to ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period, for special enrollment periods provided under § 155.420(d)(4), (5), (9), (10), (12), and (13). Since regulations already allow Exchanges and/or qualified individuals or enrollees discretion regarding which effective date rules to use for many special enrollment periods, we do not believe issuers will experience difficulty implementing this proposal.

This proposal would also help reduce confusion around binder payment deadlines, since these deadlines depend on a policy's coverage effective date. Accordingly, we propose 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 propose 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 would provide 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

[78] 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.*

prospective coverage. This change would help ensure that prospective effective dates across the Exchanges using the Federal platform are streamlined under one rule.

We seek comments on these proposals.

d. Special Enrollment Period Retroactive Coverage Effective Dates

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.[79]

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).[80] 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 pended 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 §§ 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. In 2017, HHS averaged a response time of 1 to 3 days to review consumer-submitted special enrollment period verification documents and provide consumers a response.[81] The response time in 2018 was substantially similar. Additionally, in 2018 and 2019, CMS 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.

Therefore, we propose to eliminate the option to move forward by no more than 1 month the effective date of enrollments that have been pended due to special enrollment period verification, aligning 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 propose to eliminate § 155.420(b)(5).

We also propose 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 propose 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 would 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, as they 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 would simplify issuer operations by eliminating that complexity.

Implementing a single set of binder payment rules would 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

[79] 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.

[80] Market Stabilization Rule, 82 FR at 18346.

[81] 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.*

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, our proposal to remove § 155.420(b)(5) would also remove this requirement off-Exchange.

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

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

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 certain conditions are satisfied.[82] 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.[83]

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.[84] In addition, because employees and dependents with a qualified small employer health reimbursement arrangement (QSEHRA) [85] generally must be enrolled in MEC,[86] 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.[87]

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.[88] 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 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.[89]

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, because the non-calendar year plan year special enrollment period is subject to plan category limitations for Exchange enrollees, HHS determined these limitations will further mitigate the potential risk of adverse selection in the Exchanges.

As discussed in the HRA rule preamble,[90] under section 2791 of the PHS Act, section 733 of the ERISA, and section 9831 of the Code, QSEHRAs are not group health plans [91] and so employees and their dependents with a QSEHRA do not qualify for the non-calendar year special enrollment period as currently written. Therefore, we propose 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 note that this special enrollment period also is incorporated by reference in the guaranteed availability regulations at § 147.104(b)(2). Therefore, if this approach is finalized as proposed, 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 seek comment on this proposal.

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 propose to revise paragraph (b)(1)(ii) by removing the requirement that the Exchange must initiate termination of a Medicare dual

[82] 84 FR 28888 (June 20, 2019).

[83] 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).

[84] See § 155.420(d)(14).

[85] 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.*

[86] 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.

[87] 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.

[88] 84 FR at 28955 through 28956.

[89] Id. at 28956.

[90] 84 FR at 28956.

[91] One exception to this general rule is that a QSEHRA continues to be treated as a group health plan under the PHS Act for purpose of Part C Title XI of the Social Security Act. See section 2791(a)(1) of the PHS Act.

enrollee's QHP coverage upon completion of the redetermination process specified in § 155.330. We also propose 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 to § 155.330. For more detailed discussions of these proposals, please see the preamble discussion under § 155.330.

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

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 propose to align § 155.430(d)(9) with the provisions for enrollee-initiated terminations at § 155.430(d)(2).

We seek comment on this proposal.

7. Eligibility Pending Appeal (§ 155.525)

a. Retroactive Applicability of Eligibility Pending Appeal

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. 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. Based on the experience of the FFEs and HHS appeals entity in administering this provision, we are considering changes for future rulemaking that would provide greater clarity to Exchanges, issuers, and appellants. We identify in the discussion that follows examples to illustrate issues that are not explicitly addressed in the current regulations and invite comment on them.

Should appellants who request and are granted eligibility pending appeal be permitted to enroll in any plan or otherwise be limited in any way to a particular issuer or plan category? For example, an enrollee who had been receiving APTC and CSR is redetermined ineligible for APTC and CSR for the subsequent plan year. This enrollee might select a bronze plan during open enrollment because it is the most affordable option available. However, this same enrollee may end up submitting the appeal request well after the date on which the enrollment in the bronze plan became effective. In the course of filing an appeal, the appellant may ask for eligibility pending appeal; if the request is granted, the appellant may wish to remain enrolled in the bronze plan. However, there is no ability to continue the appellant's eligibility for CSRs in such a plan.

We generally believe the appellant should have the option to remain enrolled in the bronze plan to allow for the continuation of APTC only, as well as the option to be enrolled in a silver plan offered by the same or a different issuer to allow for the continuation of both APTC and CSRs. We also believe it may be appropriate for eligibility pending appeal and the corresponding enrollment to take effect retroactively, as if the challenged redetermination had not been made. We welcome feedback on the value and implications of such flexibility. We would also welcome feedback on whether there are advantages to other options, such as allowing eligibility pending appeal and enrollment to take effect prospectively based on the date that the request for eligibility pending appeal is granted.

b. Timeliness of Filing for Eligibility Pending Appeal

Section 155.520(b) specifies that in general an applicant or enrollee must request an appeal within 90 days of the date of the eligibility determination being appealed. However, there is no similar timeliness requirement for requesting eligibility pending appeal with respect to Exchange coverage and eligibility. The preamble of the first Program Integrity Rule stated that pended benefits are offered on appeal of a redetermination, regardless of when the appellant requests the appeal within the 90-day appeal request timeframe.[92] If it is unclear whether an individual is asking for eligibility pending appeal at the time an appeal request is made; if the individual is unable to make this request absent additional information about it; or if an appeal request is filed on the 90th day of the appeal request timeframe, there may be little to no time remaining in the 90-day appeal request timeframe for the appellant to ask for eligibility pending appeal.

We considered for example whether a reasonable period may be 30 days from the date the Exchange appeals entity issues a notice to the appellant acknowledging receipt of a valid appeal request consistent with § 155.520(d), provided that the appeal had not been decided or dismissed prior to the end of that 30-day period. For example, a 30-day period might provide an opportunity for appellants to learn about the appeals process including their right to ask for eligibility pending appeal, which could occur after the appeal receipt date. We also considered whether a shorter period to make this request is preferable in order to limit downstream impacts on issuers. The more time an appellant has to make this request, the longer period of time over which an issuer could be required to make retroactive adjustments to the appellant's enrollment, premiums, and benefits. Conversely, we did not think that it was reasonable to require appellants to make a request for eligibility pending appeal on the date they submit their appeal request, since they may not be aware of this option and have a chance to weigh the financial consequences of this choice, particularly should they ultimately receive an unfavorable decision. Finally, we considered whether there ought to be a good cause exception for an appellant who does not request eligibility pending appeal within a prescribed timeframe. In the context of an untimely appeal request, § 155.520(d)(2)(i)(D) permits an applicant or enrollee to demonstrate within a reasonable timeframe as determined by the appeals entity that failure to timely submit was due to exceptional circumstances. Consideration could be given to similar exceptional circumstances such as a hospitalization, natural disaster, or another such event should an appellant fail to make a request for eligibility

[92] 78 FR at 54102.

pending appeal within a reasonable timeframe. We solicit comment on 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.

c. Life Events Occurring During the Pendency of the Appeal

When an eligibility redetermination is being appealed and eligibility pending appeal has been granted, it is possible that the appellant may subsequently experience a life event that impacts eligibility. For example, an appellant who is redetermined ineligible for APTC and CSR may appeal this redetermination and request and be granted eligibility pending appeal. If the appellant has a baby during the pendency of the appeal and reports the change in family size to the Exchange, the appellant would have her eligibility redetermined based on the addition of the newborn to the household. The regulations do not explicitly specify how an Exchange should resolve a pending appeal with eligibility pending appeal when an appellant who is receiving APTC and, as applicable, CSRs under eligibility pending appeal reports a change to the Exchange, and how the resultant eligibility from this reported change interacts with this appellant's eligibility pending appeal. We solicit comment on ways to facilitate the administration of these eligibility changes.

d. Impact of Eligibility Decision on Eligibility Pending Appeal

Appellants who are granted eligibility pending appeal may ultimately have their eligibility redetermination overturned. When a decision overturns the eligibility redetermination being appealed, under § 155.545(c)(1)(ii) the appellant has the option to have the decision implemented retroactively, to the coverage effective date the appellant did receive or would have received if they had enrolled in coverage under the incorrect eligibility (re)determination that is being appealed. In cases where the appellant is continuing to receive APTC and CSRs under a grant of eligibility pending appeal, it is possible that the decision determines the appellant eligible for a higher dollar amount of APTC and/or a higher level of CSRs than what was provided during the pendency of the appeal. We also recognize that retroactive implementation of a decision may create additional burdens on issuers who may have to re-process claims and recalculate cost-sharing amounts and out-of-pocket maximums, as well as refund premiums in excess of what the appellant paid, which an issuer may be experiencing for a second time, following implementation of a request for eligibility pending appeal. We solicit input on what if any limitations on implementation of a decision when eligibility pending appeal has been granted may be appropriate and under what circumstances.

e. Eligibility Pending Appeal and Non-Payment of Premiums

Finally, we solicit comment on how eligibility pending appeal interacts with the consequences of non-payment of premiums. The preamble to the final rule establishing § 155.525 stated that an issuer may terminate coverage as provided in § 155.430(b)(2)(ii); however, the regulations are not explicit about the applicability of the 3-month grace period as described in § 156.270(d) and (g) for appellants who are granted eligibility pending appeal. We believe that issuers and appellants may appreciate more clarity about this issue in general, as well as about how to treat appellants who may be in a grace period at the time that the redetermination is made and eligibility pending appeal request is granted. We will consider any comments we receive on this topic for future rulemaking.

We appreciate comment on these issues, as well as any others impacting the administration of eligibility pending appeal.

8. Eligibility Standards for Exemptions (§ 155.605)

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

HHS calculates the required contribution percentage for each benefit year using the most recent projections and estimates of premium growth and income growth over the period from 2013 to the preceding calendar year. We propose 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 are proposing 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).[93] This rate of income growth

[93] The 2013 and 2020 per capita personal income figures used for this calculation reflect the latest NHEA data, which was updated between the publication of the proposed rule and this final rule, on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed

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.).[94]

Thus, using the 2021 premium adjustment percentage proposed in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2020 is 1.3542376277 ÷1.3094029651, or 1.0342405385. This results 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, an increase of 0.04 percentage points from 2020 (8.27392–8.23702). We seek comment on this proposal.

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

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 Rule,[95] HHS issued regulations at §§ 155.1400 and 155.1405 to establish quality rating information display standards for Exchanges.[96] Consistent with these regulations, Exchanges must prominently display on its website, in accordance with § 155.205(b)(1)(iv) and (v), quality rating information assigned for each QHP,[97] 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 operate their own eligibility and enrollment platforms were given the option to display their respective QHP quality rating information and several of these State Exchanges voluntarily elected to display 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.[98] 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. We understand that during the QRS pilot, some State Exchanges that operate their own eligibility and enrollment platforms displayed the quality rating information as provided by HHS, while others displayed quality rating information with certain state-specific customizations in order to best reflect local priorities or information. Therefore, HHS proposes 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 some state-specific customizations, such as to incorporate additional state or local quality information or to modify the display names of the QRS star ratings. However, we clarify that State Exchanges that operate their own eligibility and enrollment platform cannot 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.[99] We believe this 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 seek comment on this proposal.

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

1. Definitions (§ 156.20)

We are proposing to remove the definition of the term ''generic'' at § 156.20 because the proposed revision at § 156.130(h) would no longer use the term ''generic''. For a discussion of that proposal, please see the preamble to § 156.130(h).

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

Section 1311(d)(5)(A) of the PPACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specified that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the

description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

[94] 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*.

[95] 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*.

[96] 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).

[97] Exchanges can satisfy the requirement to display the QHP Enrollee Survey results by displaying the QRS star ratings (which incorporate member experience data from the QHP Enrollee Survey). See 79 FR at 30310.

[98] Quality Rating Information Bulletin for Plan Year 2020. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf*.

[99] See sections 1311(c)(3) and (c)(4) of the PPACA.

monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP. In addition, OMB Circular No. A–25R establishes Federal policy regarding the assessment of user charges under other statutes and applies to the extent permitted by law. Furthermore, OMB Circular A–25R 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 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.

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 anticipated establishment of State Exchanges in certain states in which FFEs currently are operating), and premiums for the 2021 plan year, we seek comment on two alternative proposals. First, we propose 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 plan year.

Alternatively, we are considering and seek comment on reducing the FFE user fee rate below the 2020 benefit year level. This alternative proposal reflects 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 in hopes of reducing the user fee burden on consumers and creating downward pressure on premiums. We are also seeking information 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 level in the final rule. If these savings do not materialize, CMS anticipates having to increase 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 seek comment on this proposal.

As previously discussed, OMB Circular No. A–25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and Federal programs. Accordingly, in § 156.50(c)(2), we specified that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, 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.

For the same reasons we discuss above in relation to the FFE user fee rate, we are considering and seek comment on an alternative proposal to ensure HHS can cover the costs of the special benefits it will provide to SBE–FP issuers during the 2021 benefit year. First, we are proposing 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 help to ensure that user fees sufficiently cover the costs of the special benefits HHS provides to SBE–FP issuers.

Also, for the same reasons discussed above in relation to the FFE user fee rate, we are also considering and seek comment on lowering the SBE–FP user fee rate below the 2020 benefit year level. In addition, we are also seeking information 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. We seek comment on this alternative proposal.

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.

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 propose amending § 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 propose that HHS will determine which benefits are in addition to EHB for the state.

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,[100] we finalized a standard at § 155.170(a)(2) that specifies benefits mandated by state action taking place on or before December 31, 2011,

[100] 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.*

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 PTCs.

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. We also now clarify 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,[101] 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 Notice [102] 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) (Pub. L. 110–343, enacted October 3, 2008); 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, 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,[103] 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.[104] 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 affirm that here. 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 encourage states to reach out to us concerning any state defrayal questions in advance of passing and implementing benefit mandates.

HHS is aware of stakeholder concerns that there may be states not defraying the costs of their state-required benefits in addition to EHB in accordance with Federal requirements. HHS shares these concerns.

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. Issuers may be covering as EHB benefits 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 are proposing to amend § 156.111(d) and add a new § 156.111(f) to explicitly require states to annually notify HHS in a form and

[101] 81 FR at 12242.

[102] This was originally clarified in the 2016 Payment Notice, and reiterated in the 2017 Payment Notice.

[103] 83 FR 16930, at 16977.

[104] Frequently Asked Questions on Defrayal of State Additional Required Benefits (October 2018), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-Defrayal-State-Benefits.pdf.*

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).

As part of this proposed collection at § 156.111(f), we are also proposing that states identify which state-required benefits it has determined are not in addition to EHB and do not require defrayal in accordance with § 155.170, and provide the basis for the state's determination. A state's submission would be required to describe all benefits requirements under state mandates applicable to QHPs in the individual or small group market that were imposed on or before December 31, 2011 and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as all benefits requirements under state mandates that were imposed any time after December 31, 2011 applicable to the individual or small group market. For example, if a state benefit requirement applicable to QHPs in the individual or small group market was imposed before December 31, 2011, but was no longer in effect on December 31, 2011, then the state would not be expected to include that state mandate in its report. The state's report would also be required to describe whether any of the state benefit requirements in the report were amended or repealed after December 31, 2011. Information in the state's report would be required to be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

We are also proposing at § 156.111(d)(2) to specify that if the state does not notify HHS of its required benefits considered to be in addition to EHB by the annual reporting submission deadline, or does not do so in the form and manner specified by HHS, HHS will determine which benefits are in addition to EHB for the state for the applicable plan year. HHS's determination of which benefits are in addition to EHB would become part of the definition of EHB for the applicable state for the applicable plan year. We solicit comment on whether we should also allow states to affirmatively decline to report, indicating to HHS that HHS should determine which of the states' mandated benefits require defrayal.

We believe requiring states to annually report to HHS on their state-required benefits would also help states be diligent about their framework for determining which mandates are in addition to EHB in accordance with § 155.170. This proposal properly aligns with Federal requirements for defraying the cost of state-required benefits, would generally improve transparency with regard to the types of benefit requirements states are enacting, would provide the necessary information to HHS for increased oversight over whether states are appropriately determining which state-required benefits require defrayal, whether states are correctly implementing the definition of EHB, and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs.

We propose that the annual reporting of state-required benefits would begin in plan year 2021. We believe this would give states sufficient time to review the proposed requirements and prepare for submission of their annual EHB reporting package. For the first year of reporting, we propose that the deadline for states to submit to HHS their complete annual reporting package would be July 1, 2021. This would mean that for the first year of reporting, states would notify HHS in the manner specified by HHS 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). As specified below at § 156.111(f) we are also proposing states identify which state-required benefits are not in addition to EHB and do not require defrayal in accordance with § 155.170, and provide the basis for the state's determination, by the annual reporting submission deadline.

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 May 2, 2021. However, we 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. We believe that setting this cut-off date at least 60 days prior to the submission deadline would allow 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 (for example, after May 2, 2021) that happens to enact, amend, or repeal a state-required benefit after this cut-off date but before the annual reporting submission deadline (for example, before July 1, 2021) would not be expected to report that state-required benefit in that plan year's annual reporting submission. Instead, the state would be expected to include that state-required benefit in the annual reporting package for the following year. States would be permitted to submit their reports any time between the 60-day cut-off date and the applicable deadline.

As explained further below, this proposed annual reporting cut-off date would not impact a state's requirement 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.

We solicit comment on the proposed reporting deadline and 60 day cut-off date, including on whether the window between the cut-off date and submission deadline should be shortened to 30 days, and whether this reporting should be required less frequently to decrease burden on states, for example, every other year.

At § 156.111(f), we propose specifying 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. We propose that for a reporting package to be complete, it would need to comply with the following requirements. Specifically, § 156.111(f)(1) proposes that states annually reporting to HHS would be required to provide a document that is accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS that lists 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, as well as any state benefit requirements under state mandates applicable to QHPs in the individual or small group market that were imposed any time after December 31, 2011.

In the first reporting year, this document would 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 would only need 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. We will announce the annual reporting submission deadline for subsequent years in subsequent Payment Notices. If a state has not imposed, amended, or repealed any state benefit requirements during the applicable time period, the state would still be required to report to HHS that there have been no changes to state-required benefits since the previous reporting cycle. We propose that, in such a scenario, the state submit the same reporting package as the previous reporting cycle and affirmatively indicate to HHS that there have been no changes. We solicit comment on this proposal.

Section 156.111(f)(2) proposes that states annually reporting to HHS would also be required to specify which of those state-required benefits listed in accordance with § 156.111(f)(1) the state has identified as in addition to EHB and subject to state defrayal under § 155.170. We expect states to already be carefully considering state benefit requirements imposed, amended, or repealed through state action taken after December 31, 2011, to determine whether they require state defrayal in accordance with Federal requirements. We further expect that states are already defraying the costs of those benefits. As such, we expect that this information will be readily accessible to states.

Section 156.111(f)(3) proposes that states must identify in their annual reports which of the state-required benefits listed in accordance with § 156.111(f)(1) the state has identified as not in addition to EHB and not subject to defrayal, in accordance with § 155.170, and describe the basis for the state's determination. The justification that states would be required to provide under this proposal should be concise and refer to applicable Federal standards for determining whether a state-required benefit is not in addition to EHB and does not require defrayal. For example, a state could explain that a state-required benefit is not in addition to EHB and does not require defrayal because the state benefit requirement was enacted on or before December 31, 2011.

The proposal in § 156.111(f)(4) would require states to submit other information about those state-required benefits listed in accordance with § 156.111(f)(1). This information is necessary for HHS oversight and would include information such as the following: 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 § 156.111(f)(5), we propose requiring the document 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. In § 156.111(f)(6), we propose to require states to make updates to this list of state-required benefits 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.

We solicit comment generally on this proposal, including its information collection requirements, specifically with regard to whether HHS should require any additional information from states as part of the annual reporting submission on state-required benefits.

If this proposal is finalized as proposed, HHS would provide template(s) reflecting the form and manner of the report that states would be required to use for reporting the required information proposed in § 156.111(f)(1) through (6). We 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. If the state does not notify HHS of its state-required benefits that are in addition to EHB in accordance with the proposed requirements at § 156.111(f), HHS will complete a similar document for the state and post it to the CMS website. We seek comment on whether any benefit would be derived from offering a public comment period on the aforementioned documents that we plan to post to the CMS website. We are particularly interested in whether the benefit to such a comment period would outweigh publishing the final documents later in the year, as would be necessary to accommodate such a comment period.

We emphasize for states that this proposed 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 under this proposal or defer to HHS to make determinations as to which state-required benefits require defrayal. We also note that under these proposals the issuer would still be responsible for quantifying the cost of these benefits and reporting that to the state. States remain required to make payments to defray the cost of additional required benefits to the enrollee or QHP issuer on behalf of the enrollee.

We acknowledge that each state's structure likely varies for tracking, analyzing, and defraying state-required benefits in accordance with § 155.170. So long as the state's current structure for identifying state-required benefits in addition to EHB and defraying the cost of those benefits complies with § 155.170, the state may continue its current approach and need not make changes to align with the timing of the proposed annual reporting requirements at § 156.111, provided it still reports according to the timeline established under § 156.111.

We are proposing the annual reporting requirement to strengthen program integrity and to provide the necessary information to HHS for increased oversight over whether states are appropriately determining which state-required benefits require defrayal, whether states are correctly implementing the definition of EHB, and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs. However, the annual reporting proposal is also intended to be complementary to a state's current process for identifying state-required benefits in addition to EHB.

For example, a state may currently have in place a structure for identifying and defraying state-required benefits in addition to EHB where the state works

in tandem with its state legislature as bills are introduced to assess whether they contain state-required benefits that would require defrayal if passed. The same state may be working on a continual basis with actuaries to conduct actuarial analyses of the potential state-required benefits in advance of the bill's passage to anticipate the amount the state may be required to defray. If the bill passes, the same state may then collect issuers' actuarial quantifications of the state-required benefit and, depending on the effective date of the state-required benefit, immediately begin making payments to the issuer or enrollee on a monthly basis to defray the cost of the state-required benefit. Under this example, a state that annually reports to HHS would not be required to delay or modify the timing of any of these steps due to the proposed annual reporting requirement and associated deadlines. If finalized, the annual reporting requirement may function as an additional, but complementary step to those already in place at § 155.170.

Although this would remain true for a state that does not annually report to HHS by the annual submission deadline such that HHS will determine which benefits are in addition to EHB for the state, we recognize it may be best for these states to wait for HHS to post the information required in § 156.111(f)(1) through (6) on the CMS website before the state begins making payments to the enrollee or the QHP issuer to defray the costs of state-required benefits in addition to EHB. In other words, we recommend that where states defer to HHS the task of identifying state-required benefits that require defrayal, states may modify their existing timeline for defrayal as necessary to work in tandem with HHS determinations as to which of the state-required benefits are in addition to EHB.

We seek comment on the extent to which states are not appropriately identifying and defraying state-required benefits in addition to EHB to inform HHS' understanding of whether there is sufficient value in finalizing this proposal. We also solicit comment on whether states are the appropriate entities to continue making these determinations, or whether HHS should amend § 155.170(a)(3) to make the Exchanges again responsible for determining which state-required benefits are in addition to EHB, since the Exchange is responsible for certifying QHPs.

In practice, providing Exchanges with this authority would mean that the Federal government, as operator of the FFEs, would determine which state-required benefits are in addition to EHB in FFE states. State Exchanges would have the authority to make that determination in states that established their own Exchanges. We also solicit comment on whether we should instead revise § 155.170(a)(3) to make HHS the entity responsible for determining which state-required benefits are in addition to EHB in every state such that HHS would determine which state-required benefits require defrayal. Regardless of whether HHS or a state makes this determination, QHP issuers would still be responsible for quantifying the costs for these additional mandates and reporting them to the state, which would generally trigger the state's duty to make defrayal payments directly to the enrollee or the QHP issuer.

Given the proposed changes to this section, we are further proposing to rename this section ''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.

b. States' EHB-Benchmark Plan Options

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.[105] 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 propose 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 emphasize 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 recommend states submit applications at least 30 days prior to the submission deadline to

[105] 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.*

ensure completion of their documents by the proposed deadline. We also remind states that they must complete the required public comment period and submit a complete application by the deadline. We seek 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. We therefore propose 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 seek comment on the proposed deadline.

We also reiterate 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 pursuant to section 1302(2)(A) of the PPACA, and a generosity standard to establish the 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 clarify 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 clarify that the typical employer plan and generosity standard requirements are two separate tests that an EHB-benchmark plan must satisfy. However, we recognize that there may be some instances in which it may be difficult to design an EHB-benchmark plan that satisfies both standards. Therefore, we remind states that, as we stated in the *example methodology* guidance,[106] 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.

4. Essential Health Benefits Package (§ 156.130)

a. Premium Adjustment Percentage (§ 156.130)

We propose 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 Notice [107] and 2015 Market Standards Rule [108] established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage for the 2015 benefit year and beyond. Beginning with the 2015 benefit year, the premium adjustment percentage was calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the NHEA. 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).

[106] 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.*

[107] 79 FR 13743.

[108] 79 FR 30240.

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 more closely reflects 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 were to adopt the proposed change.[109]

We propose to continue to use the private health insurance premium measure (excluding Medigap and property and casualty insurance) for the 2021 benefit year. As such, we propose 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).[110] Using this formula, the proposed premium adjustment percentage for the 2021 benefit year is 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 percent over the period from 2013 to 2020.

Based on the proposed 2021 premium adjustment percentage, we propose the following cost-sharing parameters for benefit year 2021.

(1) Maximum Annual Limitation on Cost Sharing for Plan Year 2021

We propose 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 above, and the 2014 maximum annual limitation on cost sharing of $6,350 for self-only coverage, which was published by the IRS on May 2, 2013,[111] we propose 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 seek comment on this proposal.

b. Reduced Maximum Annual Limitation on Cost-Sharing (§ 156.130)

We propose 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 FPL. 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 propose above, 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. Below, we describe our analysis for the 2021 plan year and our proposed results.

(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,

[109] 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. See Revenue Procedure 2019–29, 2019–32 IRB 620. *https://www.irs.gov/pub/irs-drop/rp-19-29.pdf.*

[110] The 2013 and 2020 per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) figures used for this calculation reflect the latest NHEA data. The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed description of the NHE projection methodology is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

[111] See Revenue Procedure 2013–25, 2013–21 IRB 1110. *http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

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 Calculator [112] 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 (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (⅔ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively).

In contrast, the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL (½ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we propose 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 ⅕, rather than ½, consistent with the approach taken for benefit years 2017 through 2019. We further propose 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 ⅔, as specified in the statute, and as shown in Table 10.

These 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 note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in 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 do not propose to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent of FPL. We seek 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 10—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2021

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2020	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2020
Individuals eligible for 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

c. Cost-Sharing Requirements (§ 156.130)

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), we have received feedback that indicates there is confusion about whether § 156.130(h)(1), as finalized, requires 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. On August 26, 2019, HHS and the Departments of Labor and the Treasury released FAQ Part 40, 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 a health savings account (HSA).

Specifically, Q&A–9 of IRS Notice 2004–50 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 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. Such a requirement could put the issuer or sponsor of an HDHP in the position of complying with either the requirement under the 2020 Payment Notice for limits on cost sharing in the case of a drug manufacturer coupon for

[112] Available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.*

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.[113]

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 drug manufacturers' coupons from the annual limitation on cost sharing, including in circumstances in which there is no medically appropriate generic equivalent available.

Accordingly, we propose 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 this proposal, plans and issuers have the flexibility to determine whether to include or exclude coupon amounts from the annual limitation on cost sharing, regardless of whether a generic equivalent is available.

Consistent with this proposal, we also propose to interpret the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons. Therefore, the value of these coupons 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 expense [114] 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. Drug manufacturer coupon amounts reduce the costs incurred by an enrollee under the health plan because they reduce the amount that the enrollee is required to pay at the point-of-sale in order to obtain coverage for the drug. The value of the coupon is not a cost incurred by or charged to the enrollee; thus, we believe its value should not be required to count toward the annual limitation on cost sharing. Under this interpretation, and to the extent consistent with applicable state law, 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, would have flexibility to determine whether to include or exclude drug manufacturer coupon amounts from the annual limitation on cost sharing, regardless of whether a medically appropriate generic equivalent is available.[115] This proposal would enable issuers and group health plans to continue longstanding practices with regard to how and whether drug manufacturer coupons accrue towards an enrollee's annual limitation on cost sharing.

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 drug manufacturer coupons for brand name drugs from the annual limitation on cost sharing when a medically appropriate generic equivalent is available. We encourage issuers and group health plans to consider utilizing this proposed flexibility to find innovative methods to address the market distortion that occurs when consumers select a higher-cost brand name drug when an equally effective, medically appropriate generic drug is available.[116] We would expect issuers and group health plans to be transparent with enrollees and prospective enrollees regarding whether the value of drug manufacturer coupons accrues to the annual limitation on cost sharing as issuers' policies would affect enrollees' out-of-pocket liability under their plans. 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 seek comment on this proposal.

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,[117] 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 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 1095–A tax forms 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 trigger the mailing of corrected tax forms to consumers after tax season, creating consumer burden and confusion.

To more explicitly state requirements for issuers in the Exchanges, we propose amending § 156.265(f) to require an

[113] 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*.

[114] As defined in section 223(d)(2) of the Code.

[115] We note that an issuer or group health plan that elects to credit coupon 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.

[116] We also encourage issuers and group health plans to consider utilizing this flexibility to promote the use of biosimilars over the use of their respective reference biological product.

[117] See 77 FR 18309 at 18425.

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 propose 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. In State Exchanges on the Federal platform, references in this section to the Exchange should be understood to mean CMS, as administrator of the Federal platform. We believe these amendments will encourage more timely reconciliation and error reporting, resulting in an improved consumer experience.

6. Promoting Value-Based Insurance Design

The proposals in this section seek to promote a consumer-driven health care system in which consumers are empowered to select and maintain health care coverage of their choosing. We are proposing 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.

We are now pursuing strategies that will assist in the uptake and offering of value-based insurance design by QHP issuers. Specifically, we are outlining 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,[118] and other applicable laws such as the MHPAEA (section 2726 of the PHS Act). We are not proposing 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 Michigan [119] (the Center), Table 11 lists high value services and drugs that an issuer may want to consider offering with lower or zero cost sharing. Table 11 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 11 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 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.*[120] *The Center's research has shown that a silver level of coverage base plan could alter the cost sharing as proposed in Table* 11 *and could achieve a zero impact on plan premiums, while incentivizing the consumer to seek more appropriate care.*

TABLE 11—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 directing-acting combination
Pre-exposure prophylaxis for HIV (PrEP)[121]
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
High-cost imaging
X-rays and other diagnostic imaging
Outpatient surgical services
Non-preferred branded drugs

[118] 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.

[119] 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.*

[120] 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.*

[121] Per 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 30, 2020, in a manner consistent with the U.S Preventive

Continued

For issuers in Exchanges using the Federal platform, HHS is not proposing to offer 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 seek 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 demonstrate how the cost-sharing structures who affect different consumers, and how to assist consumers in selecting a value-based QHP if it is an appropriate option.

We are also soliciting 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 solicit comment on principles that HHS could adopt to establish what constitutes a value-based plan, perhaps establishing minimum standards, as well as obstacles to other obstacles to implementation. We are interested in additional ways in which HHS could provide operational assistance to issuers offering value-based QHPs. 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 solicit comment from states that believe their cost sharing laws would not allow for this type of plan design.

Lastly, we solicit comment on other value-based insurance design activities HHS should pursue in the future, including applicable models for stand-alone dental plans.

7. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

Issuers are currently required under § 156.270(b)(1) 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 consider a termination of coverage of a consumer whose enrollment would violate the anti-duplication provision of section 1882 of the Social Security 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.[122]

However, there are a number of scenarios where issuers are 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 propose 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.

The original version of § 156.270 required a termination notice when an enrollee's coverage was terminated ''for any reason,'' [123] with a 30-day advance notice requirement. This requirement was eventually replaced with the current requirement. As bases for termination in § 155.430(b)(2) were expanded, § 156.270 was not updated in parallel. Although we currently recommend that issuers send termination notices whenever an enrollee's coverage is terminated, questions have arisen from issuers regarding when termination notices are required. Updating our regulations to require issuers to send termination notices to enrollees for all termination events, regardless of who initiated the termination, would help streamline issuer operations and reduce confusion. This change would 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 request comments on this proposal.

8. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice,[124] 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 have found that many issuers prefer to research payment errors and use enrollment reconciliation and disputes to update their enrollment and payment data, and may be unable to complete this research and provide confirmation or dispute of their payment and collection reports within 15 days, 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 may submit disputes that are no longer necessary after the reconciliation updates have been processed.

Therefore, we propose to amend § 156.1210 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. This is captured in the new proposed § 156.1210(a).

We also propose to remove the requirement currently captured at § 156.1210(a) that issuers actively confirm payment accuracy to HHS each month, as well as the language currently captured at § 156.1210(b) regarding late filed discrepancies. We propose to instead require at new § 156.1210(b) an annual confirmation after the end of each payment year, in a form and manner specified by HHS. Issuers would also have an opportunity as part of the proposed annual confirmation process to notify HHS of disputes related to identified inaccuracies. These changes are based on our experience with current enrollment and payment operations, which include frequent updates to enrollment and payment data throughout the year, and that we believe make monthly confirmation unnecessarily burdensome.

Finally, we propose to delete the current provision at § 156.1210(c)

Services Task Force (USPSTF) final recommendation at *https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.*

[122] See 3.4.8 Medicare Enrollment and Non-renewals of the 2019 federally-facilitated Exchanges (FFEs) and federally-facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual at *https://www.regtap.info/uploads/library/ENR_EnrollmentManualForFFEandFF-SHOP_5CR_071019.pdf.*

[123] 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).

[124] See 78 FR 65045 at 65080.

related to discrepancies to be addressed in future reports. We believe that any discrepancies would already be addressed through the payment process described in the payment dispute paragraph as described in the proposed new § 156.1210 or through the adjustments to the enrollment process in § 156.265(f). Therefore, the current provision at § 156.1210(c) would be duplicative and unnecessary.

HHS intends to work cooperatively with issuers that make a good faith effort to comply with these procedures. Issuers can 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 proposed 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 solicit comment on these proposed changes.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Reporting Requirements Related to Premiums and Expenditures (§ 158.110)

We propose amending § 158.110(a) to clarify requirements for MLR purposes for issuer reporting of expenses for functions outsourced to or services provided by other entities. Such entities include third-party vendors, other health insurance issuers, and other entities, whether affiliated or unaffiliated with the issuer.

Section 2718(a) of the PHS Act requires health insurance issuers to separately report the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage. Section 158.110 codifies the general reporting requirements for issuers in the group and individual health insurance markets. However, the current regulation does not comprehensively address the reporting requirements for expenses for functions outsourced to other entities that are contracted to perform clinical and administrative activities for health insurance issuers in the group and individual markets.

Section 158.140(b)(3)(i) through (iii) specifies that issuers may not include in incurred claims amounts paid to third-party vendors for secondary network savings, and administrative costs and profits, but does not explicitly state that payment to third-party vendors for provision of clinical services may be included in incurred claims. The May 13, 2011 CCIIO Technical Guidance (CCIIO 2011–002) (May 2011 Guidance) [125] Q&A #12 clarified that issuers may include payments to third-party vendors attributable to direct provision of clinical services to enrollees in incurred claims, and that such payments to a third-party vendor may include an administrative cost component.

We note that the inclusion of a third-party vendor's administrative costs as incurred claims in this scenario is only permitted to the extent the vendor is reimbursed under a capitation arrangement, which is consistent with how capitation payments to providers (addressed in Q&A #8 in the May 2011 Guidance) are treated for MLR purposes. Q&A #14 in the May 2011 Guidance similarly clarified that payments to third-party vendors for performing health care QIA expenses on behalf of the issuer may be reported as QIA, to the extent that the issuer and the vendor can show that these activities meet the definitions in §§ 158.150 and 158.151.

However, Q&A #14 also specified that third-party vendor QIA expenses must not include the vendor's administrative costs or profits, consistently with the treatment of reporting third-party vendor incurred claims costs which is codified in § 158.140(b)(3)(ii). We note that this requirement applies regardless of whether QIA services are provided under a capitation arrangement, due to the difference in the nature of clinical services and QIA and the greater potential for abuse.

The July 18, 2011 CCIIO Technical Guidance (CCIIO 2011–004) [126] Q&A #19 further clarified that payments to third-party vendors may only be included in incurred claims to the extent the vendor provides clinical services through its own employees, and that payments to the vendor to perform administrative functions on behalf of the issuer must be reported as a non-claims administrative expense. As stated in the May 2011 Guidance, Q&A #11, an issuer that needs to include payments to third-party vendors in its MLR reporting is only required to obtain from the third-party vendor the aggregate amounts attributable to providing direct clinical services to enrollees and attributable to administrative cost and profit component of the payments, and that nothing in the regulation requires the third-party vendor to disclose proprietary data concerning pricing arrangements.

In order to consolidate and clarify the MLR treatment of payments to third-party vendors and other entities, we propose 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 seek comments on this proposal.

2. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

Section 2718(a) of the PHS Act requires health insurance issuers to, for MLR purposes, separately report the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage, on activities that improve health care quality, and on non-claims (administrative) costs. Section 158.140 sets forth the MLR reporting requirements related to the reimbursement for clinical services provided to enrollees, including a requirement that issuers must deduct from incurred claims prescription drug rebates received by the issuer. We propose to amend § 158.140(b)(1)(i) to require issuers to deduct from incurred claims prescription drug rebates and other price concessions not only when received by the issuer, but also when 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). 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.).

For example, pharmaceutical drug manufacturers often provide, either directly to issuers or indirectly through PBMs retained by issuers, prescription drug rebates and other price concessions based upon such considerations as securing a more favorable placement on

[125] Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/dwnlds/mlr-guidance-20110513.pdf.*

[126] Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/20110718_mlr_guidance.pdf.*

an issuer's drug formulary, increasing the drug utilization and market share, or limiting an issuer's exposure to drug price changes. The portion of premium revenue that an issuer expends on its enrollees' pharmacy costs (excluding the administrative costs and profits related to the provision of pharmacy benefits) is the actual reimbursement to pharmacies, less the prescription drug rebates or other price concessions secured from drug manufacturers.

For purposes of the MLR and rebate calculations, the MLR December 1, 2010 interim final rule (75 FR 74864) directed issuers to deduct from incurred claims prescription drug rebates received by issuers.[127] The MLR December 1, 2010 interim final rule additionally required issuers who outsource administration of their pharmacy benefits to PBMs (or other third-party vendors) to exclude from incurred claims the portion of payments they make to PBMs that exceeds the reimbursement to providers and thus represents the PBMs' administrative costs and profits.[128] This approach sought to ensure that issuers' spending on pharmacy benefits was treated consistently regardless of whether issuers choose to administer the benefits themselves or outsource these functions to an entity providing pharmacy benefit management services. However, the current approach provides an unfair advantage to issuers who utilize an entity to provide pharmacy benefit management services and allow the entity to retain prescription drug rebates or other price concessions.

An issuer that chooses to retain an entity to provide pharmacy benefit management services may incur administrative costs in the form of paying the entity a fee, providing the entity an inflated pharmacy reimbursement amount, and/or allowing the entity to retain a portion or all of the prescription drug rebates and other price concessions generated by the issuer's enrollees' drug utilization. The issuer may realize a profit on pharmacy benefits to the extent outsourcing pharmacy benefit management and compensating the entity in any one of the above ways is more cost-effective than providing pharmacy benefits directly. The current regulatory framework in § 158.140(b)(1)(i) and (b)(3)(i) through (iii) only accounts for the situation where the administrative costs and profits related to the provision of pharmacy benefits are comprised of an administrative fee paid by an issuer to the entity providing pharmacy benefit management services or a ''spread'' (retained by the entity) between the amount the issuer provides to the entity for pharmacy reimbursement and a lower amount the entity actually reimburses to the pharmacy. The regulation does 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 or other price concession that the issuer allows the entity providing pharmacy benefit management services to retain. In both situations, the net portion of premium revenue that an issuer expends on enrollees' pharmacy costs is the actual reimbursement to pharmacies, less prescription drug rebates or other price concessions. However, because the regulation currently requires an issuer to deduct from incurred claims prescription drug rebates only when received by the issuer and does not clearly provide that rebates and price concessions retained by an entity providing pharmacy benefit management services to the issuer must be reported in situations where the issuer allows the entity to retain a portion or all of such rebates and price concessions, the portion retained by the entity is not reflected anywhere in the MLR reporting or calculation. Consequently, under the current regulation, enrollees fail to receive the benefit of prescription drug rebates and price concessions to the extent these are retained by an entity other than the issuer. In addition, the current regulation enables issuers who compensate entities providing pharmacy benefit management services by allowing them to retain prescription drug rebates or price concessions to inflate the incurred claims and MLRs relative to financially identically situated issuers who choose to compensate these entities by paying a fee or an inflated pharmacy reimbursement amount.

Therefore, we propose 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 by the issuer, and any prescription drug rebates or 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 also propose to make conforming revisions to § 158.160(b)(2) to require issuers to report the prescription drug rebates and price concessions described above as non-claims costs. These proposed revisions would not only provide for a more equitable treatment of issuers in the commercial health insurance markets, but also align more closely with the MLR provisions that apply to the Medicare Advantage organizations and Part D sponsors and Medicaid managed care organizations,[129] both of which require that the full amount of prescription drug rebates and price concessions be deducted from incurred claims. We seek comments on all aspects of these proposals.

We propose that these amendments would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022). We seek comments regarding the applicability date to ensure that issuers have adequate time to adjust contracts with entities that provide pharmacy benefit management service to issuers to share information with those issuers about rebates and other price concessions they receive (to the extent not already required by law).

3. Activities That Improve Health Care Quality (§ 158.150)

We propose amending § 158.150(b)(2)(iv)(A)(*5*) to clarify that issuers in the individual market may include the cost of certain wellness incentives [130] as QIA expenses in the MLR calculation.

Section 2718(a)(2) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary that includes information on the percent of total premium revenue that is spent on activities that improve health care quality. A non-exhaustive list of examples of allowable wellness QIA in § 158.150(b)(2)(iv) includes the cost of certain wellness incentives offered by issuers in the group markets, but does not explicitly list wellness incentives offered in the individual market. However, issuers in the individual market are currently permitted to offer participatory wellness programs,

[127] The MLR reporting form instructions further clarify that prescription drug price concessions must be deducted regardless of the specific form they take, including prescription drug rebates, refunds, incentive payments, bonuses, discounts, charge backs, coupons, grants, direct or indirect subsidies, direct or indirect remuneration, upfront payments, goods in kinds, or similar benefits.

[128] 45 CFR 158.140(b)(3)(i) through (iii).

[129] 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.*

[130] For this purpose, the term ''wellness incentive'' has the same meaning as the term ''reward'' in § 146.121(f)(1)(i).

provided such programs are consistent with applicable state law and available to all similarly situated individuals.[131] In addition, CMS recently announced a new wellness program demonstration project through the September 30, 2019 CMS Bulletin: Opportunity for States to Participate in a Wellness Program Demonstration Project to Implement Health-Contingent Wellness Programs in the Individual Market.[132] This bulletin announced the opportunity for states to apply to participate in a 10-state wellness program demonstration project, as described in section 2705(l) of the PHS Act. Under this demonstration project, participating states may implement nondiscriminatory health-contingent wellness programs in the individual market, subject to the wellness program provisions of section 2705(j) of the PHS Act.

To ensure consumer choice and access to wellness programs, we propose to amend § 158.150(b)(2)(iv)(A)(*5*) to clarify that issuers in the individual market are allowed to include wellness incentives in the same manner as is permitted for the group market, to the extent such incentives are permitted by section 2705 of the PHS Act, as QIA in the MLR calculation.[133] We propose that these amendments would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022). We seek comment on this proposal.

4. Other Non-Claims Costs (§ 158.160)

For a discussion of the proposed amendment to § 158.160(b)(2) regarding non-claims costs other than taxes and regulatory fees, please see the preamble to § 158.140.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This proposed 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 15. 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 are soliciting 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.[134] Table 12 in this proposed 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 12—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
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 are proposing 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 would 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

[131] See the Incentives for Nondiscriminatory Wellness Programs in Group Health Plans; Final Rule; 78 FR 33158 at 33167 (June 3, 2013).

[132] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Wellness-Program-Demonstration-Project-Bulletin.pdf.* Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Wellness-Program-Demonstration-Project-Bulletin.pdf.*

[133] 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. As detailed above, 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.

[134] 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.*

benefits manager would need 1 hour (at $127.74 per hour) and a lawyer would need 0.5 hours (at $138.68 per hour) to prepare the notice. The total burden for an HRA plan sponsor would be 1.5 hours with an equivalent cost of approximately $197. This burden would be incurred the first time the non-Federal governmental plan sponsor provides an excepted benefit HRA. In subsequent years, the burden to update the notice 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.[135] The total burden to prepare the notices would be approximately 1,352 hours with an equivalent cost of approximately $177,569.

Non-Federal government sponsors of excepted benefit HRAs would provide the notice to eligible participants every year. We estimate that sponsors would provide printed copies of these notices to approximately 193,715 eligible participants annually.[136] We anticipate that the notices would be approximately 1 page long and the cost of materials and printing would be $0.05 per notice. It is assumed that these notices would be provided along with other benefits information with no additional mailing cost. We assume that approximately 54 percent of notices would be provided electronically and approximately 46 percent would be provided in print along with other benefits information. Therefore, state and local government entities providing excepted benefit HRAs to their employees would print approximately 89,109 notices at a cost of approximately $4,455 annually. We are seeking 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 previous plan year and if so, what type or magnitude of change should trigger such a subsequent notice. If the requirement is finalized such that notice must be provided only for plan years for which there is a change from the previous years, the printing and materials costs would be lower and this estimate would represent an upper bound for the annual cost after the first year.

The total burden to prepare and send the notices in the first year would be approximately $182,000. In subsequent years, under the proposal that would require an annual notice regardless of whether there was a change from the previous years, these employers would only incur printing and materials costs of approximately $4,455 annually. The average annual burden over 3 years would be 451 hours with an equivalent annual cost of $59,190, and an average annual total cost of $63,645.

TABLE 13—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	0	0	4,455
2022	901	193,715	0	0	4,455
3 year Average	901	193,715	451	59,190	4,455

C. ICRs Regarding Special Enrollment Periods (§ 155.420)

We propose to amend § 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, which is subject to pre-enrollment eligibility verification. 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 would 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.[137]

We estimate that this policy would result in relatively few additional consumers being required to submit documents to verify their eligibility to enroll through the proposed special enrollment period on or off-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 who wish to change plans mid-calendar year would be required to submit documents to confirm SEP eligibility. Additionally, because changing plans mid-calendar year would generally result in these consumers' deductibles and other cost-sharing accumulators re-setting we anticipate that few consumers will opt to do so, which will result in a minimal increase in burden for individuals with a QSEHRA that renews on a non-calendar year basis and wish to change their plans mid-calendar year. We solicit comment on whether or not this is the case.

D. ICRs Regarding Quality Rating Information Display Standards for Exchanges (§§ 155.1400 and 155.1405)

At §§ 155.1400 and 155.1405, we propose to codify the flexibility for State

[135] HHS assumes that only 1 percent of state and local government entities will offer excepted benefit HRAs.

[136] 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.

[137] 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.

Exchanges that operate their own eligibility and enrollment platforms regarding 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. We are in the process of reinstating this information collection.

E. ICRs Regarding State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

At § 156.111, we propose to require states to annually report to HHS, in a form and manner specified by HHS and by a date determined by HHS, any state-required benefits applicable to the individual and/or small group market that are considered in addition to EHB in accordance with § 155.170. States would be required to include in their initial reports information of state benefit requirements under state mandates that were imposed on or before December 31, 2011, that are applicable to QHPs in the individual or small group market and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as any state-required benefits under mandates that were imposed any time after December 31, 2011, that are applicable to QHPs in the individual or small group market. In subsequent years, states would be required to update the content in its report to add any new state benefit requirements imposed during the applicable reporting period, and to indicate whether benefit requirements previously reported to HHS were amended, repealed, or otherwise affected by state action during the reporting period. In every report, states would be required to identify which state-required benefits it has determined is in addition to EHB and subject to defrayal. States would also be required to identify which state-required benefit it has determined not to be in addition to EHB and not subject to defrayal, and would be required to describe the basis of such determinations. If the state fails to notify HHS of its required benefits considered to be in addition to EHB by applicable annual submission deadlines, or fails to do so in the form and manner specified by HHS, we propose that HHS would determine which benefits are in addition to EHB for the state.

At § 156.111(f) we propose specifying 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. Specifically, § 156.111(f)(1) proposes that states annually reporting to HHS would be required to provide a document that is accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS that lists state benefit requirements 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 any state benefit requirements under state mandates that were imposed any time after December 31, 2011 that are applicable to QHPs in the individual or small group market.

Section 156.111(f)(2) proposes that states annually reporting to HHS would also be required to specify which of those state-required benefits listed in accordance with § 156.111(f)(1) the state has identified as in addition to EHB and subject to state defrayal under § 155.170. Section 156.111(f)(3) proposes that states annually reporting to HHS be required to specify which of the state mandates listed in accordance with § 156.111(f)(1) the state has identified as not in addition to EHB and not subject to defrayal in accordance with § 155.170, and describe the basis for the state's determination. Section 156.111(f)(4) proposes that states submit other information about those state-required benefits listed in accordance with § 156.111(f)(1) that is necessary for HHS oversight, as specified by HHS.

In § 156.111(f)(5), we propose that this document be signed by a state official with authority to make the submission on behalf of the state, to confirm the accuracy of the submission. We solicit comment generally on these document collection requirements, specifically with regard to whether HHS should require any additional information from states on state-required benefits as part of the annual reporting submission. In § 156.111(f)(6), we propose to require states to make updates to this list of state-required benefits 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 are otherwise affected by state regulatory or legislative action.

If finalized as proposed, HHS would provide the template(s) that states would be required to use for reporting the required information proposed in § 156.111(f)(1) through (6). We would 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 proposed requirements at § 156.111(f), HHS would complete a similar document for the state and post it to the CMS website.

We anticipate that the majority of states would choose to annually notify 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 proposing that states report to HHS as part of this annual reporting should already be readily accessible to states, we estimate that approximately ten states would not report and the remaining states would annually report to HHS by the annual reporting submission deadline. Therefore, we estimate that approximately forty-one (41) states would respond to the information collection requirements associated with these proposals.

For the first year in which the annual reporting would take place, states would 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 would 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 would 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 proposing that states report to HHS should be readily accessible to states, we estimate that it

would 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 would 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 would 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 would 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 would be 30 hours, with an equivalent cost of approximately $2,459, with a total first year burden for all 41 states of 1,025 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 would update as necessary in future annual reporting cycles, we believe the burden associated with each annual reporting thereafter would be lower than the first year. We estimate that for each annual reporting cycle after the first year it would 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 would 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 would 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 would 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 would be approximately 697 hours with an equivalent average annual cost of approximately $64,154.

We propose to amend 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. Subject to renewal, the control number is currently set to expire on September 30, 2020. It was last approved on September 18, 2017, and remains active. Since we are not proposing 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 propose 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 also propose to amend § 158.140(b)(1)(i) to require issuers to deduct from incurred claims price concessions received 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 propose conforming amendments to § 158.160(b)(2) to require such amounts to be reported as a non-claims cost.

Finally, we propose 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 would require 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)). The control number is currently set to expire on October 31, 2020.

H. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 14—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control No.	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	1.5	451	$59,190	$63,645
§ 156.111	0938–1174	41	41	15.3	697	64,154	64,154
Total		942	193,756		1,148	123,344	127,799

Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 14.

I. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS's website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments

electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–9916–P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due April 6, 2020.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule proposes 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 proposes 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 medical loss ratio (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 proposed rule aim to ensure taxpayer money is more appropriately spent and that states have flexibility and control over their insurance markets. They would reduce regulatory burden, reduce administrative costs for issuers and states, and would 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 proposed rule would 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, would 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 Government plan sponsors offering excepted benefit HRAs would incur expenses associated with providing a notice. Issuers would experience an increase in rebates paid to consumers due to proposed 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 A–4, Table 15 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed 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 proposed rule. The effects in Table 15 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule for health insurance issuers and consumers. The annual monetized transfers described in Table 15 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers and the potential increase in rebates from issuers to consumers due to proposed amendments to MLR requirements.

We are proposing the risk adjustment user fee of $0.19 PMPM for the 2021 benefit year to operate the risk adjustment program on behalf of states,[138] which we estimate to cost approximately $50 million in benefit year 2021. We expect risk adjustment user fee transfers from issuers to the Federal Government to remain steady at $50 million, the same as estimated for

[138] As noted earlier in this proposed 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.

the 2020 benefit year; this is included in Table 15.

Additionally, for 2021, we are considering two alternative proposals. First, we are proposing maintaining the FFE and the SBE–FP user fee rates at current levels, 3.0 and 2.5 percent of premiums, respectively. Alternatively, we are considering and seek comment on reducing the user fee rates below the 2020 plan year levels.

TABLE 15—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 proposals 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)	−$50.48 −$47.66	2019 2019	7 3	2020–2024 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 $283,000 in 2020 and approximately $50,000 2021 onwards. • Reduction in potential costs to Exchanges since they would not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be one-time savings of $44 million in 2020 and annual savings of $92 million in 2020 and 2021. • Regulatory familiarization costs of approximately $54,000 in 2020.				
Qualitative: • Increased costs due to increases in providing medical services (if health insurance enrollment increases). • Potentially minor costs to Exchanges and DE partners to update the application and logic to account for new plan options for Exchange enrollees newly ineligible for CSRs and enrollees covered by a non-calendar plan year QSEHRA. • Potential reduction in costs to issuers due to elimination of duplicative coverage as part of PDM. • Potential reduction in costs to consumers due to PDM noticing efforts to notify enrollees of duplicative coverage and risk for tax liability. • Potential costs to the Exchanges and consumers to comply with the new special enrollment period requirements. • Potential reduction in burden for Exchanges and issuers to comply with the proposed special enrollment period prospective coverage effective dates.				
Transfers	**Estimate million**	**Year dollar**	**Discount rate (percent)**	**Period covered**
Annualized Monetized ($/year)	$14.1 14.3	2019 2019	7 3	2020–2024 2020–2024
Quantitative: • Net increase in transfers from health insurance issuers to consumers in the form of rebates of $18.2 million per year due to proposed amendments to the MLR requirements.				
Qualitative: • 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 would 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 16 or 17. Table 16 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2020 through 2024, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of tZhis proposed rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 16.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions proposed in this rule are consistent with our previous estimates in the 2020 Payment Notice for the impacts associated with the APTCs, the

premium stabilization programs, and FFE user fee requirements.

TABLE 16—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FISCAL YEAR 2020–2024, IN BILLIONS OF DOLLARS [139]

Year	2020	2021	2022	2023	2024	2020–2024
Risk Adjustment and Reinsurance Program Payments ..	5	6	6	6	6	29
Risk Adjustment and Reinsurance Program Collections	5	6	6	6	6	29

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.
Source: Congressional Budget Office. *Federal Subsidies for Health Insurance Coverage for People Under Age 65: Tables From CBO's May 2019 Projections* Table 2. May 2, 2019. Available at *https://www.cbo.gov/system/files/2019-05/51298-2019-05-healthinsurance.pdf.*

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 are proposing 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 would provide employees with clear information regarding excepted benefit HRAs offered by their employers. Excepted benefit HRAs sponsored by non-Federal Government entities would incur costs to provide the notice as detailed previously in the Collection of Information Requirements section.

2. Early Retiree Reinsurance Program (Part 149)

Our proposal to remove the regulations at part 149 of title 45 governing the ERRP would not have any direct regulatory impact since the ERRP sunset as of January 1, 2014. However, removing the regulations would 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 propose to use 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 remain steady from the prior 2020 benefit year estimates of approximately $50 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 $50 million, and the risk adjustment user fee would be $0.19 PMPM. Because overall risk adjustment contract costs estimated for the 2021 benefit year are similar to 2020 benefit year costs, we do not expect the proposed risk adjustment user fee for the 2021 benefit year to materially impact transfers from issuers of risk adjustment covered plans to the Federal Government.

Additionally, to use risk adjustment factors that reflect more recent treatment patterns and costs, we propose to 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 propose to discontinue our reliance on MarketScan® data to recalibrate the risk adjustment models, and to adopt and maintain an approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk adjustment models beginning with the 2021 benefit year and beyond. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients would 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 also propose to incorporate several proposed HCC changes into the 2021 benefit year risk adjustment models. We do not expect these proposals 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 (§ 153.630)

Under § 153.630, we are proposing changes to the requirements for RADV. Beginning with the 2019 benefit year of RADV, we propose to 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 would 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 also propose 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. We are proposing this second pilot year to 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 proposal to affect the magnitude of RADV adjustments to risk adjustment transfers, or to impact issuer

[139] Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

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)

In future rulemaking, we intend to propose amendments to § 155.320(d)(4)(i) to remove the requirement that Exchanges use random sampling as part of its program to verify whether an applicant for insurance affordability programs (for example, APTC and CSRs) is enrolled in or eligible for employer-sponsored coverage. We intend to propose amendments under which Exchanges will have the flexibility to design their employer-sponsored coverage verification programs based on a fulsome assessment of the risk for inappropriate payments of APTC and CSRs, which would be based on reliable studies, research, and analyses of an Exchange's own enrollment data. We believe this flexibility would benefit employers, employees, Exchanges using the Federal platform, and State Exchanges that operate their own eligibility and enrollment platform because it would eliminate the burden of investing resources to conduct and respond to random sampling.

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 this study 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 be 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 be approximately $4.5 million for State Exchanges that operate their own eligibility and enrollment platform, for a total cost of $54 million for the 12 State Exchanges that operate their own eligibility and enrollment platform (operating in 11 States and the District of Columbia).

We are aware, however, 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 would 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 would be approximately $44 million. We estimate the annual costs to conduct sampling on a statistically significant sample size of approximately 1 million cases to be approximately $6 million to $8 million for the Exchanges using the Federal platform and State Exchanges that operate their 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. We estimate that average recurring cost for each State Exchange that operates its own eligibility and enrollment platform to conduct sampling would be $7 million, and the total annual cost for the Exchanges using the Federal platform and the 12 State Exchanges that operate their own eligibility and enrollment platform would be $92 million. Relieving Exchanges of the requirement to conduct sampling for plan years 2020 and 2021 would therefore result in annual savings of approximately $92 million. We seek comment on this estimate.

In addition to significant cost savings, these future plans would provide more flexibility for states to design and implement a verification process for employer-sponsored coverage that is tailored to their unique populations, and would protect the integrity of states' respective individual markets. Furthermore, we believe that this future change would reduce burden on employers and employees, as the current random sampling, notification, and information gathering processes required significant time and resources to comply with, and likely would be reduced under the alternative approach we are exploring.

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

We propose to amend § 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 would 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 would also streamline the termination process. Additionally, we believe this proposal would safeguard consumers against being enrolled in unnecessary or duplicative coverage. The proposal could 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 would provide Exchanges with more flexibility in their operations.

HHS requests comment on the impacts of this proposal.

We propose to 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 would reduce the amount of time a deceased enrollee remains in QHP coverage while receiving APTC/CSRs. Additionally, we believe this proposal would 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 proposal might help streamline Exchanges' PDM operations, as eligibility redeterminations are not necessary when termination of coverage is for a deceased enrollee, and would provide Exchanges with more flexibility in their operations.

We request comment on the impacts of this proposal.

7. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for CSRs

We propose to amend § 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. We anticipate that this would 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 it might help impacted 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. Relatedly, this proposal might also provide some benefit to the individual market risk pool by making it easier for applicable enrollees to maintain continuous coverage in spite of potentially significant changes in their out-of-pocket health care costs. Regardless, we believe that this change would not have a negative impact on the individual market risk pool, because most applicable enrollees would be seeking to change coverage based on financial rather than health needs. However, this proposal would impose a small cost to Exchanges that have implemented plan category limitations, because it would 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 solicit comments on the extent to which Exchanges would experience burden due to this proposed change.

Finally, because it represents a change to current system logic, this proposal might impose some burden on FFE Direct Enrollment and Enhanced Direct Enrollment partners. We solicit comment on this matter, as well as more generally, on the impact this proposal.

b. Special Enrollment Period Limitations for Enrollees Who Are Dependents

We believe that our proposal to add a new § 155.420(a)(4)(iii)(C) would not impose burden on Exchanges, because it would streamline the rules at § 155.420(a)(4) by ensuring that all existing enrollees are treated in the same way, and therefore might simplify implementation. We also anticipate that it would 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 seek comment from Exchanges on whether this is the case, and if not, on the costs that this 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 impacted by this type of plan category limitation.

c. Special Enrollment Period Prospective Coverage Effective Dates

The proposal to transition special enrollment periods currently following regular effective date rules to instead be effective on the first of the month following plan selection in Exchanges using the Federal platform would 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 would 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 would reduce burden for both issuers and Exchanges. We seek comment on these expectations.

d. Special Enrollment Period Retroactive Coverage Effective Dates

Our proposal to eliminate 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 would 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 current § 155.400(e)(1)(iii), issuers already receive transactions for retroactive coverage and assign coverage effective dates either retroactively or prospectively based on consumer payments. Our proposed change would 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 would not incur costs based on this change.

We seek comment on these expectations.

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

We anticipate that the proposal to amend § 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 would 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 would 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 proposal would impose limited burden on FFE Enhanced Direct Enrollment partners, because required changes for these partners would be limited to updating application question wording.

Additionally, while this proposal would provide QSEHRA enrollees an opportunity to change their individual health insurance plan, we believe that uptake would be limited as most eligible employees would 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 would 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 solicit comments on this proposal, including from Exchanges, on implementation burden and costs.

8. Effective Dates for Terminations (§ 155.430)

As discussed earlier in the preamble to § 155.430, our proposal would 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 would 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 proposal would 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 anticipate our proposal to amend §§ 155.1400 and 155.1405 to codify the flexibility to State Exchanges that operate their own eligibility and enrollment platforms, to customize the display of quality rating information on their websites would 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 star ratings.

10. FFE and SBE–FP User Fees (§ 156.50)

For 2021, we are considering two alternative proposals. First, we are proposing 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 are considering and seeking comment on reducing the user fee rates below the 2020 benefit year levels. If the user fees are lowered below the 2020 plan 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.

11. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We are proposing to amend § 156.111(d) and add a new § 156.111(f) to explicitly require states to annually notify HHS in a form and manner specified by HHS by a date determined by HHS of 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. We are also proposing at § 156.111(d)(2) to specify that if the state does not notify HHS of its state-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 determine which benefits are in addition to EHB for the state for the applicable year. We also propose to specify at § 156.111(f)(1) through (6) the type of documentation states would be required to submit as part of the annual reporting, which among other requirements would 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. We recognize that this proposal would require states annually reporting to HHS to 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 would be minimal and that this reporting requirement would 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 are proposing this annual reporting requirement because we are concerned that there may be states not defraying the costs of their state-required benefits in addition to EHB in accordance with Federal requirements. We therefore acknowledge that there may be states that do not currently have in place an effective process for tracking, analyzing, and identifying state-required benefits applicable to QHPs in the individual and/or small group markets for purposes of determining whether they are in addition to EHB and require defrayal. For such states, the burden might be higher to meet the annual reporting requirement. However, we believe the proposed 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. This proposal properly aligns with Federal requirements for defraying the cost of state-mandated benefits, would generally improve transparency with regard to the types of benefit requirements states are enacting, and would provide the necessary information to HHS for increased oversight over whether states are appropriately determining which state-required benefits require defrayal, whether states are correctly implementing the definition of EHB, and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs. Because we believe the information we are proposing that states report to HHS as part of this annual reporting should already be readily accessible to states, we believe any burden would 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 do not anticipate these proposals would add any new burden on states that do 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, as they would be relying on HHS to make these determinations and fill out these templates for them. We acknowledge that the HHS determination of which requirements are in addition to EHB and therefore require defrayal might conflict with the opinion of a state that does not annually report to HHS. Because we are also proposing that HHS's determination of which benefits are in

addition to EHB would become part of the definition of EHB for the applicable state for the applicable year, this might require states to defray more benefits than the state currently defrays or anticipated having to defray. As such, in the former scenario, the annual reporting proposal might 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 proposal would cause a state to newly defray the cost of state-required benefits it should have always been defraying in accordance with § 155.170 but was neglecting to do so, this would 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. 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. In the event that the annual reporting proposal 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 might decrease the amount of PTC for enrollees in the state as the percent of premium allocable to EHB would be reduced.

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 set forth in this proposed rule the reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analysis in previous Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the PPACA to the estimated 2021 maximum annual limitation on cost sharing for self only coverage of $8,550. We do not believe the proposed changes to the maximum annual limitation on cost sharing or the reductions in this parameter for silver plan variations would result in a significant economic impact.

We also propose the premium adjustment percentage for the 2021 benefit year. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the Affordable Care Act: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b). 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) is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these proposed updated values would 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' Coupons (§ 156.130)

In this proposed rule, we propose to revise § 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 proposal would 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.

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,[140] 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 propose 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 also propose to amend § 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 State Exchanges on the Federal platform, referenced in this section to the Exchange should be understood to mean CMS, as administrator of the Federal platform. We believe these amendments would encourage more timely reconciliation and error reporting, resulting in an improved consumer 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 would 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,[141] 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 proposing to amend § 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 do not believe that this proposal would have any impact on issuer burden, beyond what was

[140] See 77 FR 18309 at 18425.

[141] See 78 FR 65045 at 65080.

previously estimated in the 2014 Payment Notice.

16. Medical Loss Ratio (§§ 158.110, 158.140, 158.150, and 158.160)

In this proposed rule, we propose to amend § 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 proposal to change the impact as it does not change the existing requirements. We also propose to amend § 158.140(b)(1)(i) to require issuers to deduct from incurred claims price concessions received by the issuer, as well as prescription drug rebates and other price concessions attributable to the issuer's enrollees and received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer, and propose conforming amendments to § 158.160(b)(2) to require such amounts to be reported as non-claims costs. 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 proposal could 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 proposal 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. We additionally propose to amend § 158.150(b)(2)(iv)(A)(*5*) to 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 proposal could decrease rebate payments from issuers to consumers by $0.2 million per year.

17. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this 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 last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed 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 proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that we are required to 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.[142] Assuming an average reading speed, we estimate that it would take approximately 1 hours for the staff to review the relevant portions of this proposed rule that causes unanticipated burden. We assume that 497 entities will review this proposed 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 $54,352 ($109.36 x 497 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this proposed rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

For the proposal to amend 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 would provide these consumers with important information about their excepted benefit HRA.

Instead of proposing to delete the regulations in part 149, governing the ERRP, we considered taking no action and leaving the regulations in place. We believe this alternative is less desirable than repealing the regulations, which would reduce the overall volume of Federal regulations.

In proposing 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 preamble, we are not proposing to add these additional categories.

Regarding proposed 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 would 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 our 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 HHS Navigators and other enrollment assisters, as well as from agents and brokers, the current policy likely prevents some enrollees from

[142] *https://www.bls.gov/oes/current/oes_nat.htm.*

maintaining continuous coverage for themselves and for their dependents due to a potentially significant change to their out of pocket costs. Under our proposal, an enrollee impacted 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 coinsurance cost sharing requirements could change to a gold-level plan. HHS believes that this policy would likely have minimal impact on the individual market risk pool because most applicable enrollees would 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 above, 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 proposed 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 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 sub-regulatory 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) and (d)(8) and (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 the proposed regulatory change is necessary to align all prospective special enrollment periods under one effective date rule.

In proposing to align retroactive effective date and binder payment rules under § 155.400(e)(1)(iii), we considered eliminating both § 155.400(e)(1)(v) (as we propose), but revising, rather than eliminating, § 155.420(b)(5). Section 155.420(b)(5) provides 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 propose 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, would also have the option to effectuate coverage with the applicable prospective coverage.

Under this proposed rule, a consumer could 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 for this proposal), 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,[143] 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 developing the proposal for annual reporting of state-required benefits in addition to EHB, we considered a variety of alternatives, including making no modifications. 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, neither of these options would offer HHS direct insight into the frequency with which states require benefits in addition to EHB to be covered. Further, we believe that requiring states to annually report to HHS on their state-required benefits applicable to QHPs in the individual and/or small group market will also help states be diligent about their framework for determining which mandates are in addition to EHB in accordance with § 155.170. This proposal properly aligns with Federal requirements for defraying the cost of state-mandated benefits, would generally improve transparency with regard to the types of benefit requirements states are enacting, and would provide the necessary information to HHS for increased oversight over whether states are appropriately determining which state-required benefits require defrayal, whether states are correctly implementing the definition of EHB, and whether QHP issuers are properly allocating the portion of premiums

[143] 84 FR 28888.

attributable to EHB for purposes of calculating PTCs.

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 making this determination 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 determining which state-required benefits are in addition to EHB in every state such that HHS would always determine 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 so long as the annual reporting requirement demonstrates to HHS that states are complying with § 155.170, states should remain the entity responsible for making these determinations. We solicit comment on all aspects of the annual reporting proposal at § 156.111 and specifically whether a different approach would be preferable.

In proposing to amend § 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, we are instead proposing to refer broadly to the reasons listed in § 155.430(b).

For the proposed 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 changes to this section would ensure that it is interpreted consistently and that issuers therefore face a level playing field. We also believe that changes to this section would generally increase consumer choice and access to wellness programs, as well as ensure that there would be no obstacles to HHS implementing a demonstration project under which individual market issuers would be permitted to offer certain health-based wellness programs.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this proposed rule, we propose 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.[144] 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 report[145] 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 proposed amendments to the MLR provisions of this proposed rule in part 158. Therefore, we do not expect the proposed MLR provisions of this rule to 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 would offer employees an excepted benefit HRA, and would therefore 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 603 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 proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this would 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

[144] *https://www.sba.gov/document/support--table-size-standards.*

[145] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

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. Currently, that threshold is approximately $154 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed 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 proposed rule would not impose substantial direct requirement costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. We are also proposing to require 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 proposed requirements in this rule.

We also believe this regulation has federalism implications due to our proposals regarding clarifications regarding the PDM process, 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 proposed 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 would not impose new requirements on State Exchanges that operate their own eligibility and enrollment platform, but rather provides 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 to our two proposals related to plan category limitations: (1) Our 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 select a QHP one metal level higher or lower if they elect to change their QHP enrollment; and (2) to add 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 might 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 request 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 these two proposals.

Additionally, we expect that our proposal to amend § 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 would 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, might 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 request comment on these expectations.

We also believe that there may be federalism implications related to the proposed requirement for states to annually notify HHS, in a form and manner specified by HHS, of 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 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, would be relying on HHS to make these determinations. We acknowledge that the HHS determination of which requirements are in addition to EHB and therefore require defrayal might conflict with the opinion of a state that does not annually report to HHS. Such concerns are mitigated however because states can avoid such a result by submitting the proposed report.

We do not anticipate any federalism implications related to our proposal 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 proposed changes, State Exchanges could 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 our proposal to remove the separate

retroactive effective date rule for enrollments pended due to special enrollment period verification under § 155.420(b)(5). Neither the retroactive binder payment rule specific to enrollments pended 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 current § 155.420(b)(5) does apply to State Exchanges, a State Exchange that has implemented special enrollment period verification would 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 proposal to require 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 proposal 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.

H. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review. This proposed rule is 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 new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

This proposed rule, if finalized as proposed, is expected to be E.O. 13771 deregulatory action. We estimate cost savings of approximately $135.66 million in 2020 and $91.95 million in 2021 and annual costs of approximately $50,000 thereafter. Thus the annualized value of cost savings, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, would be 10.55 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 proposes to amend 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 [DATE 30-DAYS AFTER THE EFFECTIVE DATE OF THE FINAL RULE], 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) 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 him 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 him 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 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 determine which benefits are in addition to EHB for the applicable plan year in the State, consistent with § 155.170(a)(3) 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 drug manufacturer coupons.* 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) 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) Confirm 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 2021, prescription drug rebates received by the issuer;

(B) Beginning with the 2021 MLR reporting year, prescription drug rebates and other price concessions received and retained by the issuer, or 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 2021 MLR reporting year, prescription drug rebates and other price concessions that are received and retained by the issuer, or 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: October 24, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 7, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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