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DEPARTMENT OF THE TREASURY

31 CFR Part 33

RIN 1505-AC72

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

[CMS-9914-P]

RIN 0938-AU18

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations

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

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth payment parameters and provisions related to the risk adjustment program; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It includes proposed changes related to special enrollment periods; Navigator program standards; direct enrollment entities; the administrative appeals processes with respect to health insurance issuers and non-federal governmental group health plans; the medical loss ratio program; acceptance of

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payments by issuers of individual market Qualified Health Plans; and other related topics. It proposes clarifications to the regulation imposing network adequacy standards with regard to Qualified Health Plans that do not use provider networks. It proposes changes to the regulation requiring the reporting of certain prescription drug information by qualified health plans or their pharmacy benefit managers. It also proposes a new direct enrollment option for Federally-facilitated Exchanges and State Exchanges. This proposed rule also proposes changes related to section 1332 State Innovation Waivers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[Insert date 30 days after the date of filing for public inspection at the OFR].**

ADDRESSES: In commenting, please refer to file code CMS-9914-P.

Comments, including mass comment submissions, must be submitted in one of the following 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-9914-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.

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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-9914-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, Grace Bristol, (410) 786-8437, Kiahana Brooks, (301) 492-5229, or Ken Buerger, (410) 786-1190, for general information.

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

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

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

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

Joshua Paul, (301) 492-4347, Renee O'Neill, (410) 786-8821, or Ruthanne Romero, (410) 786-8757, for matters related to risk adjustment data validation.

Dan Brown, (434) 995-5886, for matters related to web-brokers or direct enrollment,

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other than the direct enrollment option for Federally-facilitated and State Exchanges.

Robert Yates, (301) 492-5151, for matters related to the direct enrollment option for Federally-facilitated and State Exchanges.

Emily Ames, (301) 492-4246, for matters related to termination notices.

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

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

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

Ken Buerger, (410) 786-1190, for matters related to EHB-benchmark plans, defrayal of state-required benefits, network adequacy standards, and PBM transparency reporting requirements.

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

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

Leigha Basini, (301) 492-4380, for matters related to acceptance of payments by QHP issuers.

Nidhi Singh Shah, (301) 492-5110, for matters related to the Quality Rating System and the Qualified Health Plan Enrollee Experience Survey.

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

Adrienne Patterson, 410-786-0696, for matters related to netting of payments under 45

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CFR 156.1215 and administrative appeals under 45 CFR 156.1220.

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

Lina Rashid, (443) 902-2823, Michelle Koltov, (301) 492-4225, or Kimberly Koch, (202) 622-0854 for matters related to State Innovation Waivers.

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.

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I. Executive Summary

American Health Benefit Exchanges, or “Exchanges,” are entities established under the Patient Protection and Affordable Care Act (PPACA)¹ 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-Exchange.

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

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”.

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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, within the limitations of current law, we propose 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 would provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs. The proposals would also provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

Risk adjustment continues to be a core program in the individual and small group markets both on and off Exchanges, and some of the major proposals in this rule include proposed recalibrated parameters for the HHS-operated risk adjustment methodology. We also propose changes to the risk adjustment models to include a two-stage specification in the adult and child models, add severity and transplant indicators interacted with hierarchical condition category (HCC) counts factors to the adult and child models, and modify the enrollment duration factors in the adult models. Additionally, we propose to allow states to request multi-year state risk adjustment transfer reductions of up to 3 years, as well as clarifications to the process for HHS to audit and conduct compliance reviews of issuers of risk adjustment covered plans and reinsurance-eligible plans.

As we do every year in the HHS notice of benefit and payment parameters, we propose

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updated parameters applicable in the individual and small group markets. We propose the 2022 benefit year user fee rates for issuers offering plans through the Exchanges using the Federal platform. We propose lowering the Federally-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE-FP) user fees rates to 2.25 and 1.75 percent of total monthly premiums, respectively, in order to reflect enrollment, premium and HHS contract estimates for the 2022 plan year. We also propose user fee rates of 1.5 percent of total monthly premiums for FFE and SBE-FP states that elect the proposed direct enrollment option discussed later in the preamble.

In addition, we propose the 2022 benefit year premium adjustment percentage, required contribution percentage, and maximum annual limitations on cost sharing, including those for cost-sharing reduction (CSR) plan variations. These updates, required by law, will raise the annual limit on cost sharing for 2022 relative to the annual limit on cost sharing for 2021, thereby increasing cost sharing and out-of-pocket spending for consumers who will incur total costs close to the annual cost-sharing limit in the 2022 benefit year. For the 2023 benefit year and beyond, we also propose to publish these parameters in guidance annually, and if not in guidance, in the annual notice of benefit and payment parameters. Additionally, we propose clarifications to the process under which HHS audits QHP issuers related to advance payments of the premium tax credit (APTC), CSRs, and user fees.

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

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operational readiness reviews applicable to direct enrollment entities.

Stable and affordable Exchanges with healthy risk pools are necessary for ensuring consumers maintain stable access to health insurance options. In order to minimize the potential for adverse selection in the Exchanges, we are sharing our future plans for rulemaking under which we will propose requirements related to Exchange verifications of whether applicants for QHP coverage with APTC or CSR have access to employer sponsored coverage that is affordable and offers minimum value. Until we engage in future rulemaking, we propose to extend our current enforcement posture under which Exchanges may exercise flexibility not to implement risk-based employer sponsored coverage verification and to remove the requirement that Exchanges select a statistically random sample of applicants when no electronic data sources are available.

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

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

We propose to release additional data from the QHP Enrollee Experience Survey (QHP Enrollee Survey). We also solicit comments on potential changes to the framework for the Quality Rating System (QRS) to support alignment with other CMS quality reporting programs and to further balance the individual survey and clinical quality measures on the overall quality scores. We are considering ways to modify the hierarchical structure for the QRS, which is how

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the measures are organized together for maximum simplicity and understanding of the quality rating information provided by the QRS.

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

We propose to further regulate the standards related to QHP issuers' acceptance of payments for premiums and cost sharing. We also propose to make clarifications to the network adequacy rules to reflect that § 156.230 does not apply to indemnity plans seeking QHP certification.

We propose to establish a new direct enrollment option under which a State Exchange, State-based Exchange on the Federal platform or an FFE state (through an agreement with HHS) can leverage the potential of direct enrollment to offer consumers an enhanced QHP shopping experience. Under this option, instead of operating a centralized enrollment website, states could use direct enrollment technology to establish direct pathways to QHP issuers and web-brokers, through which consumers would apply for and enroll in a QHP and receive a determination of eligibility for APTC and CSRs.

We propose to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for medical loss ratio (MLR) reporting and rebate calculation purposes. We additionally propose to explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and the filing of the MLR Annual Reporting Form, and propose to establish a safe harbor allowing such issuers, under certain

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conditions, to defer the payment of any remaining rebates owed after prepayment until the following MLR reporting year. We also propose to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Lastly, we propose to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a public health emergency (PHE) declared by the Secretary of HHS in the 2021 benefit year and beyond, when such credits are permitted by HHS.

In this proposed rule, the Secretaries of HHS and the Department of the Treasury propose to reference and incorporate specific guidance published in the **Federal Register** in order to give states certainty regarding the requirements to receive and maintain approval by the Departments for State Innovation Waivers under section 1332 of the PPACA.

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 plans² 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 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.

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Section 2702 of the PHS Act, as added by the PPACA, establishes requirements for guaranteed availability of coverage in the group and individual markets, including qualifying events that trigger special enrollment periods under section 2702(b) of the PHS Act.³

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

Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group insurance market requirements contained in Part A of title XXVII of the PHS Act with respect to health insurance issuers when a state does not have authority to enforce or fails to substantially enforce these provisions and with respect to group health plans that are non-federal governmental plans.

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

³ Before enactment of the PPACA, HIPAA amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

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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. Section 1302(b) of the PPACA directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

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

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

Sections 1311(b) and 1321(b) of the PPACA provide that each state has the opportunity to establish an individual market Exchange that facilitates the purchase of insurance coverage by

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qualified individuals through QHPs and meets other standards specified in the PPACA. Section 1321(c)(1) of the PPACA directs the Secretary to establish and operate such Exchange within states that do not elect to establish an Exchange or, as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014.

Section 1311(c)(1) of the PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs, including network adequacy standards at section 1311(c)(1)(B) of the PPACA. Section 1311(d) of the PPACA describes the minimum functions of an Exchange. 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)(1) 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 Act⁴.

Section 1311(c)(3) of the PPACA directs the Secretary to develop a system to rate QHPs offered through an Exchange, based on relative quality and price. Section 1311(c)(4) of the PPACA requires the Secretary to establish an enrollee satisfaction survey that evaluates the level of enrollee satisfaction of members with QHPs offered through an Exchange, for each QHP with more than 500 enrollees in the prior year. Further, sections 1311(c)(3) and 1311(c)(4) of the PPACA require Exchanges to provide this quality rating information⁵ to individuals and

⁴ 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 PPACA.

⁵ 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").

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employers on the Exchange's website.

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

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

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 establishes federal policy regarding user fees and

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specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public.

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

Section 1321(d) of the 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 1332 of the PPACA provides the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) with the discretion to approve a state's proposal to waive specific provisions of the PPACA, provided the state's section 1332 waiver plan meets certain requirements. The Department of Health and Human Services and the Department of the Treasury (collectively, the Departments) finalized implementing regulations on February 27, 2012 (76 FR 13553) and published detailed guidance on the Department's application of section 1332 to proposed state waivers on October 24, 2018 (83 FR 53575).

Section 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 QHPs offered through

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the individual market Exchanges. This section also provides for reductions in cost sharing for American Indians enrolled in QHPs at any metal level.

Section 1411(c) of the 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) of the PPACA 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 Secretary of the Treasury, the Secretary of Homeland Security, and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations.

Section 1411(f)(1)(B) of the 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 use or disclosure of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs.

Section 5000A of the Code, as added by section 1501(b) of the PPACA, requires individuals to have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act (Pub. L. 115-97, December 22, 2017)

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the individual shared responsibility payment has been reduced to \$0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under 45 CFR 155.305(h) or 45 CFR 156.155.

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

1. Premium Stabilization Programs⁶

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit

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.

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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).

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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 HHS-RADV process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

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

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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 **Federal Register** (77 FR 17220 through 17252) and in the March 8, 2016 **Federal Register** (81 FR 12204 through 12352). This final rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. This final rule permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance 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 **Federal Register** (77 FR 17219) and in the December 22, 2016 **Federal Register** (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 **Federal Register**

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>.

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(77 FR 17219) and the December 22, 2016 **Federal Register** (81 FR 94058). This final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

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

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

In the June 2, 2020 **Federal Register** (85 FR 33595), we published a proposed rule that proposed updates to various aspects of the HHS-RADV methodologies and processes. These updates included revisions to the HCC failure rate grouping algorithm, the introduction of a sliding scale adjustment in HHS-RADV error rate calculation, the introduction of a constraint on risk score adjustments for low-side failure rate outliers, and the transition from the prospective application of HHS-RADV adjustments to an application of HHS-RADV results to risk scores from the same benefit year as that being audited.

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

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2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the “first Program Integrity Rule” published in the August 30, 2013 **Federal Register** (78 FR 54069) and the “second Program Integrity Rule” published in the October 30, 2013 **Federal Register** (78 FR 65045). In the December 27, 2019 **Federal Register** (84 FR 71674), we published a final rule that revised standards relating to oversight of Exchanges established by states and periodic data matching frequency.

3. Market Rules

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

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the Market Stabilization final rule that was published in the April 18, 2017 **Federal Register** (82 FR 18346), we released further guidance related to

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guaranteed availability. In the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 17058), we clarified that certain exceptions to the special enrollment periods only apply with respect to coverage offered outside of the Exchange in the individual market.

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

On April 8, 1997 an interim final rule with comment period was published in the **Federal Register** (62 FR 16894) that implemented the HIPAA health insurance reforms by adding 45 CFR parts 144, 146, and 148. Included in those regulations were enforcement provisions. In the June 10, 1997 **Federal Register** (62 FR 31669), we published technical corrections to these interim final rules. After gaining some experience with direct federal enforcement in some states, we determined that it was necessary to provide more detail on the procedures that will be used to enforce HIPAA when a state does not do so. On August 20, 1999, an interim final rule with comment period was published in the **Federal Register** (64 FR 45786) that provided more detail on the procedures for enforcing title XXVII of the PHS Act, as added by HIPAA, and as amended by the Mental Health Parity Act of 1996 (Pub. L. 104-204, September 26, 1996), the Newborns' and Mothers' Health Protection Act of 1996 (Pub. L. 104-204, September 26, 1996), and the Women's Health and Cancer Rights Act of 1998 (Pub. L. 105-277, October 21, 1998), when a state does not enforce such laws. We published a final rule on November 25, 2005 in the **Federal Register** (70 FR 71020) that finalized this interim final rule, and made non-substantive amendments to the regulations detailing procedures for enforcing title XXVII of the PHS Act.

5. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on

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November 18, 2010. In the July 15, 2011 **Federal Register** (76 FR 41865), we published a proposed rule with proposals to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and Small Business Health Options Program (SHOP), eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

In the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541), we set forth standards related to Exchange user fees. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In the May 11, 2016 **Federal Register** (81 FR 29146), we published an interim final rule with amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058). In the March 8, 2016 **Federal Register** (81 FR 12203), the final 2017 Payment Notice codified State Exchanges on the Federal platform along with relevant requirements. In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special

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

6. Essential Health Benefits

On December 16, 2011, HHS released a bulletin⁹ that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

The 2015 Payment Notice final rule, established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage. Beginning with the 2015 benefit year, the premium adjustment percentage was calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the National Health Expenditure Accounts (NHEA), which are calculated by the

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

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CMS Office of the Actuary. In the 2020 Payment Notice final rule, we amended the methodology for calculating the premium adjustment percentage by estimating per capita insurance premiums as private health insurance premiums, minus premiums paid for Medigap insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees. Additionally, in response to public comments to the proposed 2021 Payment Notice, the 2021 Payment Notice final rule included a policy stating that we will finalize payment parameters that depend on NHEA data, including the premium adjustment percentage, based on the data that are available as of the publication of the proposed rule for that benefit year, even if NHEA data are updated between the proposed and final rules.

In a proposed rule published in the July 15, 2020 **Federal Register** (85 FR 42782), HHS, along with the Departments of Labor and the Treasury, proposed using the premium adjustment percentage as one alternative in setting the parameters for permissible increases in fixed-amount cost-sharing requirements for grandfathered group health plans.

7. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal**

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Register (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164) and an interim final rule was published in the September 2, 2020 **Federal Register** (85 FR 54820).

8. Quality Rating System and Enrollee Satisfaction Survey

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

9. State Innovation Waivers

Section 1332(a)(4)(B) of the PPACA requires the Secretaries to issue regulations regarding procedures for State Innovation Waivers. On March 14, 2011, the Departments

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 2021,” September 2020. Available at <https://www.cms.gov/files/document/quality-rating-system-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf>.

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published the “Application, Review, and Reporting Process for Waivers for State Innovation” proposed rule¹² in the **Federal Register** (76 FR 13553) to implement section 1332(a)(4)(B) of the PPACA. On February 27, 2012, the Departments published the “Application, Review, and Reporting Process for Waivers for State Innovation” final rule¹³ in the **Federal Register** (77 FR 11700) (hereinafter referred to as the “2012 Final Rule”). On October 24, 2018, the Departments issued the “State Relief and Empowerment Waivers” guidance¹⁴ in the **Federal Register** (83 FR 53575) (hereinafter referred to as the “2018 Guidance”), which superseded the previous guidance¹⁵ published on December 16, 2015 in the **Federal Register** (80 FR 78131) and provided additional information about the requirements that states must meet for waiver proposals, the Secretaries’ application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. On November 6, 2020, the Departments issued an interim final rule¹⁶ in the **Federal Register** (85 FR 71142), which revises regulations to set forth flexibilities in the public notice requirements and post-award public participation requirements for State Innovation Waivers under section 1332 of the PPACA during the COVID-19 PHE.

B. Stakeholder Consultation and Input

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

¹² <https://www.govinfo.gov/content/pkg/FR-2011-03-14/pdf/2011-5583.pdf>.

¹³ <https://www.govinfo.gov/content/pkg/FR-2012-02-27/pdf/2012-4395.pdf>.

¹⁴ <https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf>.

¹⁵ <https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf>.

¹⁶ <https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency>

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numerous topics, particularly risk adjustment and the direct enrollment option for FFEs and State Exchanges.

We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states, and health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received as we developed the policies in this proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 147, 150, 153, 155, 156, 158, and 184. In addition, the regulations outlined in this proposed rule governing State Innovation Waivers under section 1332 of the PPACA at 45 CFR part 155 subpart N would also be codified in 31 CFR part 33.

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

The proposed changes to 45 CFR part 150 would make minor procedural changes to the requirements for administrative appeals of CMPs by health insurance issuers and non-federal governmental group health plans to align with current practices for the Departmental Appeals Board. We propose to make parallel changes to the requirements for administrative appeals of CMPs by QHP issuers under 45 CFR part 156, subpart J.

The proposed changes to 45 CFR part 153 would recalibrate the HHS risk adjustment models consistent with the approach outlined in the 2020 Payment Notice to transition away from the use of MarketScan[®] data. However, we propose to use the enrollee-level EDGE data from 2016, 2017 and 2018, the same data used for the 2021 model recalibration. We also propose changes to the HHS risk adjustment models to include a two-stage specification in the

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adult and child models, add severity and transplant indicators interacted with HCC counts factors in the adult and child models, and modify the enrollment duration factors in the adult models. In addition, we propose to clarify risk adjustment reporting requirements for issuers that choose to offer premium credits, if permitted by HHS for future benefit years. In order to provide greater market predictability, we propose to allow states to request a reduction of risk adjustment transfers for multiple years and set forth the request from Alabama to reduce risk adjustment transfers for the 2022 benefit year. Additionally, we propose clarifications to the process for HHS to audit issuers of risk adjustment covered plans and reinsurance-eligible plans and also propose to establish authority for HHS to conduct compliance reviews of these issuers. The proposals in part 153 also relate to the risk adjustment user fee for the 2022 benefit year. We also propose to revise the schedule for the collection of HHS-RADV charges and disbursement of payments such that these charges and disbursements will occur in the same calendar year in which HHS-RADV results are released. Finally, the proposals regarding part 153 include a proposal to shorten the discrepancy reporting windows for HHS-RADV, update the applicable regulations regarding when second validation audit (SVA) findings can be disputed or appealed, expand the conflict of interest standard for IVA Entities, and codify two previously established exemptions from the requirement to participate in HHS-RADV.

We propose to amend the definition of direct enrollment technology provider and add a definition of QHP issuer direct enrollment technology provider in part 155 to recognize that QHP issuers may also use QHP issuer direct enrollment technology providers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230, and make conforming amendments to the definition of web-broker. We also propose changes to web-broker website display requirements, and propose to codify more specific operational readiness review requirements for web-brokers

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and direct enrollment entities. In addition, we propose allowing Navigators and certified application counselors (CACs) to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker non-Exchange websites under certain circumstances. We also propose to amend the marketing and display requirements for direct enrollment entities.

We also propose to establish a new direct enrollment option for State Exchanges, SBE-FPs and FFE states to use direct enrollment technology and non-Exchange websites developed by approved web brokers, issuers and other direct enrollment partners to enroll qualified individuals in QHPs offered through the Exchange.

We also propose several amendments to special enrollment period policy. Specifically, we propose: to add a new flexibility to allow current Exchange enrollees and their dependents to change to a QHP of a lower metal level if they qualify for a special enrollment period due to becoming newly ineligible for APTC; to allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to select a plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event; and to clarify that a special enrollment period is triggered when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage, and the employer contributions for such coverage completely cease. We also propose to require Exchanges to verify eligibility for at least 75 percent of special enrollments for consumers newly enrolling in Exchange coverage.

As we do every year in the annual 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

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adjustment percentage. Additionally, we propose to amend part 156 to establish that for the 2023 benefit year and beyond, we will publish the annual updates to the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing and required contribution percentage in guidance in January of the benefit year prior to the applicable benefit year, rather than in the applicable benefit year's annual HHS notice of benefit and payment parameters, as long as no change to the methodologies to calculate these amounts are proposed. We also propose a methodology for analyzing the impact of preliminary values of the reduced annual maximum limitations on cost sharing on the AVs of silver plan variations. Additionally, we propose clarifications to the process for HHS to audit QHP issuers related to APTC, CSRs, and user fees and propose to establish authority for HHS to conduct compliance reviews to ensure compliance with Federal APTC, CSRs, and user fee standards. We propose to update the user fee rates for the 2022 benefit year for all issuers participating on the Exchanges using the Federal platform. We also propose modifications to the regulations addressing network adequacy standards for non-network plans and payments accepted by QHP issuers. Finally, we propose to require QHP issuers to accept premium payments made on behalf of an enrollee from an individual coverage health reimbursement arrangement (individual coverage HRA) or QSEHRA.

The proposed changes to part 158 would establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes. The proposed changes to part 158 would also explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and filing the MLR Annual Reporting Form, and establish a safe harbor allowing

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such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, the proposed changes to part 158 would allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Lastly, we propose to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS.

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

The proposed changes in 31 CFR part 33 and 45 CFR part 155 related to State Innovation Waivers would reference and incorporate the existing 2018 Guidance into regulations in order to give states certainty regarding the requirements to receive and maintain approval by the Departments.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2022 – Department of Health and Human Services

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

1. Guaranteed Availability of Coverage (§ 147.104)

Section 147.104(b)(2) incorporates by reference certain Exchange special enrollment periods described in § 155.420, making those special enrollment periods applicable to non-grandfathered coverage offered in the individual market through or outside of an Exchange. We propose amendments to § 147.104(b)(2) to clarify that paragraph (b)(2)(ii) does not apply to references in § 155.420(d)(4) (relating to errors of the Exchange), and to make a conforming

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amendment consistent with the proposal in § 155.420(c)(5) relating to special enrollment period availability for individuals who do not receive timely notice of a triggering event.

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

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

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

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

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

1. Technical Corrections

Part 150 sets forth our enforcement processes for all the requirements of title XXVII of the PHS Act with respect to health insurance issuers and non-federal governmental group health plans. This proposed rule would make technical corrections to multiple sections of part 150. Specifically, we propose removing all references to “HIPAA” and replacing them with “PHS Act” to clarify that the part 150 processes are used for enforcing not only the requirements emanating from HIPAA, but also the PPACA and other legislation enacted subsequent to

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HIPAA. These proposed wording changes were made in the February 27, 2013 **Federal Register** final rule entitled “Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” (78 FR 13406). However, because of an oversight, some references were not updated at that time. In this rule, we propose this change to the definition of “Complaint” in § 150.103; the introductory text to § 150.303(a), as well as to §§ 150.205(e)(2); 150.213(b); 150.305(a)(1), (a)(2), (b)(1) and (c)(1); 150.311(g) and 150.313(b).

2. Administrative Hearings

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

We seek comment on these proposals.

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

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.¹⁷ 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.¹⁸ We did not receive any requests from states to operate risk adjustment for the 2022 benefit year; therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2022 benefit year.

We propose changes in this rule to the identification of the 3 benefit years of enrollee-level EDGE data that would be used for purposes of the annual recalibration of the risk adjustment models. We also propose modeling updates to improve the models' predictive power for certain subgroups of enrollees, as well as proposed changes to the enrollment duration factors for the adult models, and we propose to continue a pricing adjustment related to the Hepatitis C drugs. We propose to allow states to submit multi-year requests for reductions to transfer calculations under the state payment transfer formula and we outline the 2022 benefit year reduction request submitted by Alabama. Additionally, we propose to clarify risk adjustment reporting requirements for issuers that choose to offer premium credits, if permitted by HHS for future benefit years. We propose the risk adjustment user fee for the 2022 benefit year and

¹⁷ 42 U.S.C. 18063.

¹⁸ Also see 42 U.S.C. 18041(c)(1).

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propose to codify in regulation the previously established exemptions from HHS-RADV requirements for issuers with only small group market carryover coverage in the benefit year being audited and for sole issuers in a state market risk pool during the benefit year being audited. We also propose to revise the schedule for the collection of HHS-RADV charges and disbursement of payments such that these charges and disbursements will occur in the same calendar year in which HHS-RADV results are released. Finally, we propose to shorten the discrepancy reporting windows during HHS-RADV, clarify and expand the conflict of interest standards that will be applied to initial validation audit (IVA) entities, and update the risk adjustment regulations to more clearly reflect the limitations on the ability to dispute or appeal SVA findings.

1. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXC) beginning with the 2018 benefit year.¹⁹ 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

¹⁹ For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult risk adjustment models. See, for example, 83 FR 16941.

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is multiplied by a CSR adjustment that accounts for differences in induced demand at various levels of cost sharing.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the state transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable state market risk pool. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Updates to Data Used for Risk Adjustment Model Recalibration

Consistent with the approach outlined in the 2020 Payment Notice to no longer rely upon MarketScan[®] data²⁰ for recalibrating the risk adjustment models, we propose to continue to recalibrate the risk adjustment models for the 2022 benefit year using only enrollee-level EDGE data. However, rather than using 2017, 2018 and 2019 enrollee-level EDGE data, we propose to use the 2016, 2017, and 2018 enrollee-level EDGE data (the same years' data used to recalibrate the 2021 risk adjustment models) to recalibrate the risk adjustment models for the 2022 benefit year. We also propose to continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2022 benefit year model recalibration.

Previously, we used the 3 most recent years of MarketScan[®] data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. Then, starting with the 2019 benefit year, we began transitioning from using the MarketScan[®] data to using the enrollee-level

²⁰ 84 FR 17463 through 17466.

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EDGE data to recalibrate the risk adjustment models. The 2021 benefit year was the first year that we recalibrated the risk adjustment models using 3 years of enrollee-level EDGE data.²¹ Specifically, for the 2021 benefit year, we used the 2016, 2017, and 2018 benefit years of enrollee-level EDGE data to recalibrate the risk adjustment models. During prior recalibrations, we implemented an approach that used blended, or averaged, coefficients from 3 years of separately solved models to provide stability for the risk adjustment coefficients year-to-year, while reflecting the most recent years' claims experience available. In some prior years, this approach resulted in reliance on data that could not be incorporated into the coefficients until after the publication of the applicable benefit year's Payment Notice, because the associated data was not available in time to incorporate into the models in time for publication in the Payment Notice.²² For example, due to the timing of the proposed 2021 Payment Notice, we were unable to incorporate the 2018 benefit year enrollee-level EDGE data into the proposed coefficients in the proposed 2021 Payment Notice, and instead included draft coefficients in the proposed rule reflecting only 2016 and 2017 benefit years' enrollee-level EDGE data.²³ We were also unable to incorporate the 2018 benefit year enrollee-level EDGE data in the final coefficients in the 2021 Payment Notice; therefore, consistent with § 153.320(b)(1)(i), we released the final 2021 benefit year coefficients in guidance after publication of the 2021 Payment Notice.²⁴ We followed a similar approach in other benefit years when we were unable to incorporate the most recent year of available data in the applicable benefit year's Payment Notice.²⁵

²¹ 85 FR 29173 through 29175.

²² See, for example, the 2018 Payment Notice final rule, 81 FR 94058; and the 2021 Payment Notice final rule, 85 FR 29173 through 29175.

²³ See 85 FR 7097 through 7098 and 7104 through 7112.

²⁴ See 85 FR 29173 through 29175. Also see <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>.

²⁵ See, for example, the 2018 Payment Notice rule, 81 FR 94084. Also see <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf>.

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Some commenters to the proposed 2021 Payment Notice expressed concern about when the final blended coefficients would be available, asking that final coefficients be made available earlier. Having the risk adjustment coefficients for the upcoming benefit year available earlier allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year. Commenters offered suggestions for ways HHS could propose coefficients using all of the data years that HHS would use for the final coefficients. Stakeholders submitted similar comments in prior years when the final coefficients were released in guidance after publication of the applicable benefit year's Payment Notice.²⁶ We have continued to consider these comments and, in this rulemaking, we propose to change our approach for identifying the 3 most recent years of enrollee-level EDGE data that would be used to recalibrate the risk adjustment models. Previously, we used the three most recent years of data that are available in time for publication in the final rule or soon thereafter in guidance. However, beginning with the 2022 benefit year, we are proposing to use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the data in the draft recalibrated coefficients published in the proposed rule and we propose to not update the coefficients between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available for incorporation. The purpose of this proposed change is to respond to stakeholders' request to provide the proposed coefficients in the proposed rule while continuing to use the 3 most recent consecutive years of enrollee-level EDGE data available to recalibrate the risk adjustment models. We believe this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration. This proposed

²⁶ See, for example, 81 FR 94084 through 94085.

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approach also would continue to use actual data from issuers' individual and small group (or merged) market populations, as well as maintain year-to-year stability in risk scores as the recalibration would continue to use at least two years of enrollee-level EDGE data that were used in the previous year's models.²⁷

For these reasons, we propose to use 2016, 2017, and 2018 benefit years' enrollee-level EDGE data for the 2022 benefit year model recalibration. We seek comment on our proposal to determine coefficients for the 2022 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data and our proposed approach to identify the 3 most recent years of data available for the annual recalibration of the risk adjustment models moving forward. Additionally, we seek comment on whether we should instead maintain the approach that would use the 2017, 2018, and 2019 benefit years' data to recalibrate the risk adjustment models for the 2022 benefit year.

The draft coefficients listed below in Tables 1 through 6 reflect the use of 2016, 2017, and 2018 benefit year enrollee-level EDGE data, as well as other risk adjustment model updates proposed in this proposed rule (including changes to the model specifications, changes to the enrollment duration factors and the pricing adjustment to Hepatitis C drugs). However, we note that the coefficients could change if the proposed recalibration policies, or other proposed modeling parameters, are not finalized or are modified in response to comments. In addition, consistent with § 153.320(b)(1)(i), if we are unable to finalize the final coefficients in time for the final rule, we would publish the final coefficients for the 2022 benefit year in guidance soon after the publication of the final rule.

²⁷ As detailed earlier, the 2022 benefit year recalibration would rely on the same 3 years of enrollee-level EDGE data that were used in the 2021 benefit year. For the 2023 benefit year and beyond, the recalibration would rely on 2 years of the enrollee-level data that were used in the prior year.

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b. Risk Adjustment Model Updates

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

(1) Changes to the model specifications

Beginning with the 2022 benefit year, we are proposing to modify the adult and child models specifications to improve prediction for enrollees at both the low and highest ends of expected expenditures. The current HHS-HCC models are estimated by a weighted least squares regression.²⁸ The dependent variable is annualized simulated plan liability expenditures, and the weight is the person-specific sample eligibility fraction. The effective outcome is that the models predict per member per month (PMPM) expenditures.

As described in the 2021 Payment Notice, the current HHS-HCC models, which are linear models, modestly underpredict plan liability for enrollees without HCCs (enrollees with low expected expenditures) and modestly underpredict plan liability for enrollees with the highest HCC counts.²⁹ In the 2021 Payment Notice, we described options that we were considering to address these issues, such as adding a non-linear term or HCC counts terms to the risk adjustment models.³⁰ For the non-linear model option, we considered adding a coefficient-

²⁸ See, for example, 78 FR 15420 and Section 3.7 of the "March 31, 2016 HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper," March 24, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

²⁹ 85 FR 29188 and 29189.

³⁰ Ibid.

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weighted sum of payment HCCs raised to a power that could be interpreted as a measure of overall disease burden. For the HCC counts model option, we considered adding eight indicator variables corresponding to 1 to 8-or-more payment HCCs, similar to the CMS-HCC risk adjustment counts models used for Medicare Advantage.³¹ We have further evaluated the performance of these options, their potential for improved prediction, and considered other alternatives to improve the HHS risk adjustment models' prediction.

Our initial analyses showed that the non-linear and HCC counts models would yield considerable gains in predictive accuracy in the adult models across several groups when compared to the current linear models.³² We tested both the count and non-linear models' impact on the adult silver risk adjustment models and found that the enrollees in the lowest cost deciles had better predictive ratios under either the HCC counts or non-linear model specification than under the current linear model specification. However, both models had shortcomings that prompted us to consider alternate model options. For the HCC counts model, we were concerned that the presence of counts across all HCCs may promote gaming in coding practices. We explored ways to assure modeling convergence across all metals and data years, and found that the non-linear models did not consistently converge in all testing scenarios, and that convergence could not reliably be assured without constraining model factors and revising those techniques with each metal and data year model run. Therefore, we continued to explore additional types of model specifications refinements that could balance the goals of improving the models' prediction with mitigating modeling complexity and gaming concerns. Specifically, as described later in this section, we explored a two-stage specification with additional weighting in the

³¹“Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model,” December 20, 2018. Available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part1.pdf>.

³² 85 FR 7101 through 7104.

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second stage based on the inverse capped prediction from the first stage (“two-stage specification”), a specification with HCC counts included for a small number of severe and transplant HCCs (“interacted HCC counts factors”), and an approach combining the two-stage specification with the interacted HCC counts factors.

For the two-stage specification, we explored calibrating the adult and child models in two stages: in the first-stage estimation, the model coefficients would be estimated using the current model specifications; and in the second stage, we would re-estimate the model weighted by the reciprocal of the predicted values of relative expenditures from the first step estimation with the same model specification.³³ The first stage of the weighted estimation method involves a linear regression (weighted by the person-specific eligibility fraction of the number of months enrolled divided by 12) of simulated plan liability on age-sex factors, payment HCC factors, the enrollment duration factors,³⁴ and RXCs for the adult models. For the child models, the first stage of the weighted estimation method involves a linear regression of simulated plan liability on age-sex factors and payment HCC factors. The second stage involves using the reciprocal of first-stage predictions as weights for a second linear regression.³⁵ To stabilize the weights for the second stage estimation, we imposed lower and upper bound caps on the first-stage predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. We tested various caps for the weights based on the distribution of costs, and found these lower and upper bound caps achieved better prediction on average. This approach has the

³³ This weighted approach is similar to the weighted least squares approach with the weight equal to the reciprocal of the estimated variance that is often used to correct for heteroskedasticity. However, in our proposed approach, we would use the reciprocal of predictions from the first step as weights to correct for underprediction of low-valued coefficients.

³⁴ We are proposing to modify the enrollment duration factors in the adult models, as described elsewhere in this proposed rule.

³⁵ Under the two-stage specification and interacted HCC counts model proposal described later in this section, we are proposing to replace the severity illness indicators in the adult risk adjustment models with the interacted HCC counts.

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material effect of weighting the healthier enrollees, who represent a majority of enrollees in the individual and small group (including merged) markets but who are underpredicted by the current models, more heavily so that the statistical model predicts their expenditures more accurately. On the other hand, this approach systematically underweights, and therefore underpredicts, very expensive enrollees. However, the capped weighting approach mitigated the potential to underpredict at the high end for expensive enrollees, as well as any possible low-end overprediction. In our consideration of this option, we tested various weights, including reciprocals of square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of these alternative weighting functions.

We also explored how the addition of severe and transplant indicators interacted with HCC counts, wherein an indicator flagging the presence of at least one severe or transplant payment HCC is being interacted with counts of the enrollee's payment HCCs.³⁶ The goals for this approach were to: (1) address the non-linearity in costs between enrollees with no or very low costs and enrollees with high costs; (2) empirically incorporate the cost impact of multiple complex diseases; and (3) mitigate the gaming concerns with the HCC counts model. We tested different types of severity and transplant indicators interacted with HCC counts with the goal of improving prediction for enrollees with the highest costs and multiple HCCs to counter balance the reciprocal prediction weights that relatively underpredicted costs for these enrollees. For this approach, we assessed the HCCs for enrollees with extremely high costs, and HCCs that were being underpredicted in the current risk adjustment models. We found that many of the HCCs

³⁶ For HCCs in a group, the group is counted at most once. These groups of HCCs in the risk adjustment models are typically detailed in the Tables 6 and 7 of the HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software.

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that were flagged as being underpredicted were those HCCs in the severe illness indicators, the transplant HCCs, and other HCCs related to severity of disease; therefore, we considered dropping the current severity illness indicators in the adult models and replacing them with severity and transplant indicators interacted with HCC counts factors in the adult and child models. Table 3 lists the HCCs that were selected for the severity and transplant indicators for the adult and child models for purposes of exploring this option. The severity and transplant indicators were then interacted with HCC counts factors, which are described below.

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

Under this approach, when an enrollee has a severity indicator HCC in Table 3, the enrollee’s risk score includes the sum of: (1) severity HCC variable coefficient³⁷; and (2) applicable severity HCC counts variable coefficient. The HCC counts factors, which indicate the counts of all payment HCCs for an enrollee with at least one HCC, interacted with the severity indicator in Table 3, range from one, two, to 10+ payment HCCs (1, 2, ..., 10+) for the adult models, and from one, two, to 5, then 6 or 7, and 8+ payment HCCs for the child models. To implement the severity indicator HCC counts factors and further explore this option, we removed

³⁷This is in addition to the HCC coefficients for any other HCCs that the enrollee has, as well other risk adjustment factors that the enrollee has (such as demographic factors). If an enrollee has no severe HCCs the severe count interaction term coefficients are not applicable.

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the current severe illness indicators in the adult models, and added severity indicator interacted HCC counts variables for the adult and child models.

For the transplant-related HCCs within the severity indicator HCC counts in Table 3,³⁸ we found separating out transplant HCCs into their own additional indicator to interact HCC counts factors improved prediction for these high-cost enrollees. Therefore, for the transplant HCCs, we created a separate transplant indicator to interact with payment HCC counts of 4, 5, 6, 7, or 8+ for the adult models, and a single indicator variable of payment HCC counts of 4+ for the child models. For example, an adult enrollee with a transplant HCC 34 “Liver Transplant Status/Complications” in the transplant indicator group and three other payment HCCs received the following factors toward their risk score in the adult models: (1) the four coefficients for their individual HCCs (the three non-transplant HCCs and the HCC 34 transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC counts of 4 coefficient.³⁹ The child model operated similarly. For a child enrollee with a transplant HCC in the transplant indicator group and three other payment HCCs, the following was used to calculate the enrollee’s risk score: (1) coefficients for all four HCCs, (including the transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC counts of 4 coefficient.

As an alternative, we explored interacting the HCC counts factors with each selected severity and transplant HCC, but found it was sufficient to interact the HCC counts factors with a variable indicating the presence of at least one of the selected HCCs in each group to improve

³⁸ We note that one transplant HCC (HCC 18 Pancreas Transplant) is not included on the list in Table 3. HCC 18 has a much lower coefficient than any of the other transplant HCCs in the adult models and was not underpredicted by the models. Therefore, we propose to exclude it from the list in Table 3 and solicit comments on the proposed treatment of HCC 18.

³⁹ This is in addition to other risk adjustment factors that the enrollee has (such as demographic factors).

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prediction for enrollees with these HCCs. We also explored different combinations of HCC counts to identify the counts factors for both indicator groups in the adult and child models that provided the best balance of reasonable sample sizes and relative cost differences between each counts factor. More specifically, in the adult models, we found that starting with 4+ HCCs for the transplant interacted factors improved predictions of enrollees at the very high end in terms of risk and cost and ending at 8+ HCCs instead of 10+ HCCs addressed the small sample sizes of enrollees with a transplant and 9 or more payment HCCs. For the child models, we found having one variable for 4+ payment HCCs provided more stable estimates given the smaller sample sizes for children than those for adults.

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

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

The coefficients presented in Tables 1 and 2 incorporate these proposed changes and Table 3 provides the list of severity and transplant HCCs that apply for the interacted HCC counts factors. We seek comment on these proposals, including on the HCCs selected for

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flagging as severity and transplant indicators listed in Table 3 such as whether we should include HCC 18 Pancreas Transplant in the transplant indicator group, and the alternatives described above. We also request comment on whether we should pursue both the interacted HCC counts factors and the two-stage specification beginning with the 2022 benefit year (as proposed), if we should implement one of the two approaches beginning with the 2022 benefit year (and if so, which one), or if we should wait to implement the proposed changes that combines the proposed model specification updates until the 2023 benefit year.

c. Changes to the Enrollment Duration Factors

In this rule, we propose changes to the enrollment duration factors in the adult risk adjustment models to improve the prediction for partial year enrollees with HCCs. As described in the proposed 2021 Payment Notice, we have been considering potential adjustments to the enrollment duration factors and previously analyzed the current factors using the 2016 and 2017 enrollee-level EDGE data.⁴⁰ We explored heterogeneity (variations) of costs for partial year enrollees in the presence of certain diagnosis codes, by market (individual or small group),⁴¹ and under various enrollment circumstances, such as enrollment beginning later in the year or ending before the end of the year. Our preliminary analysis of 2017 enrollee-level EDGE data found that the current enrollment duration factors are driven by enrollees with HCCs. That is, partial year enrollees with HCCs had higher PMPM expenditures on average as compared to full year enrollees with HCCs. On the other hand, partial year enrollees without HCCs were not significantly different in PMPM expenditures compared to full year enrollees without HCCs. In the 2021 Payment Notice, we also explained that our preliminary analysis found that, in

⁴⁰ See 85 FR 7103 and 7104.

⁴¹ In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

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comparison to the effect of the presence of HCCs on enrollment duration factors, enrollment timing (for example, enrollment at the beginning of the year compared to enrollment after open enrollment period, or drop in enrollment before the end of the year) did not appear to affect PMPM expenditures on average. While we did not make changes to the enrollment duration factors in the 2021 Payment Notice, we stated that we were considering eliminating the monthly enrollment duration factors up to 11 months and replacing them with monthly enrollment duration factors up to 6 months for enrollees with HCCs. We also stated that we intended to review the trends observed in our preliminary analysis using an additional year's data before proposing changes.

Since the publication of the 2021 Payment Notice, we have reassessed enrollment duration factors for adults using the 2018 benefit year enrollee-level EDGE data. The additional data year's findings were consistent with our prior finding that partial year enrollees without HCCs do not have PMPM expenditures that are significantly different compared to full year enrollees without HCCs. We also found that the current enrollment duration factors underpredict plan liability for partial year adult enrollees with HCCs, and overpredict plan liability for partial year adult enrollees without HCCs. Therefore, beginning with the 2022 benefit year, we are proposing to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, and add new monthly enrollment duration factors of up to 6 months to the adult models that would only apply for enrollees with payment HCCs. If finalized as proposed, this would mean there would be no enrollment duration factors for adult enrollees without payment HCCs starting with the 2022 benefit year adult models. As part of this analysis, we also considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between markets on average once we implemented the

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proposed enrollment duration factors of up to 6 months for adult enrollees with payment HCCs. Therefore, we are not proposing enrollment duration factors for the adult models by market type at this time. We are also proposing to continue to incorporate enrollment duration factors only in the adult models.⁴² We solicit comment on the proposed changes to the enrollment duration factors for the adult models. We also seek comment on whether we should implement these model changes starting with the 2022 benefit year, whether we should delay implementation until the 2023 benefit year, or whether we should create the enrollment duration factors for different lengths, such as up to 9 months of enrollment, instead of up to 6 months, as proposed.

d. Pricing Adjustment for the Hepatitis C Drugs

For the 2022 benefit year models, we propose to continue applying the market pricing adjustment to the plan liability associated with Hepatitis C drugs that has been in place beginning with the 2020 benefit year final risk adjustment models.⁴³ We continue to believe this market pricing adjustment is necessary to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration benefit year. We also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score that is higher than the actual plan liability of the drug claim, and therefore, make the risk adjustment transfer results more favorable for the issuer. We previously stated that we intended to reassess this pricing adjustment with future benefit years'

⁴² As explained in the 2021 Payment Notice proposed rule, we found that partial year enrollees in the child models did not have the same risk differences as partial year enrollees in the adult models and they tended to have similar risk to full year enrollees in the child models. In the infant models, we found that partial year infants had higher expenditures on average compared to their full year counterparts; however, the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors and did not have a meaningful impact on the general predictive accuracy of the infant models. See 85 FR 7103 and 7104.

⁴³ 84 FR 17463 through 17466.

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enrollee-level EDGE data.⁴⁴ We remain committed to doing so. However, we are proposing to use the same 3 years of enrollee-level EDGE data for the 2022 benefit year model recalibration as those used for the 2021 benefit year. Therefore, we propose to continue making the market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the 2022 benefit year models.⁴⁵ We intend to reassess this pricing adjustment in future recalibrations with additional years of enrollee-level EDGE data. We seek comment on this proposal.

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

The proposed 2022 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2016, 2017, and 2018 enrollee-level EDGE data, including all of the proposed model changes detailed above, are shown in Tables 1 through 6. 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.⁴⁶ Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC-HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 2 contains the factors for each child model. Table 3 lists the HHS-HCCs in the proposed severity and transplant indicator flags selected for the interacted HCC counts factors that would apply to the adult and child models beginning with the 2022 benefit year. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant models' maturity and severity categories, respectively.

⁴⁴ 85 FR 29185.

⁴⁵ The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

⁴⁶ As detailed below, we are not proposing changes to the high-cost risk pool parameters for the 2022 benefit year. Therefore, as proposed, we would maintain the \$1 million threshold and 60 percent coinsurance rate.

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

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21-24, Male	0.179	0.134	0.098	0.070	0.068
	Age 25-29, Male	0.184	0.138	0.102	0.074	0.073
	Age 30-34, Male	0.214	0.162	0.120	0.087	0.085
	Age 35-39, Male	0.248	0.188	0.140	0.100	0.097
	Age 40-44, Male	0.277	0.213	0.159	0.114	0.111
	Age 45-49, Male	0.310	0.240	0.182	0.131	0.128
	Age 50-54, Male	0.393	0.316	0.249	0.191	0.188
	Age 55-59, Male	0.446	0.359	0.285	0.221	0.217
	Age 60-64, Male	0.524	0.427	0.343	0.270	0.265
	Age 21-24, Female	0.292	0.223	0.167	0.125	0.123
	Age 25-29, Female	0.319	0.244	0.183	0.138	0.136
	Age 30-34, Female	0.375	0.290	0.221	0.165	0.162
	Age 35-39, Female	0.428	0.336	0.258	0.194	0.190
	Age 40-44, Female	0.484	0.383	0.297	0.223	0.218
	Age 45-49, Female	0.507	0.401	0.309	0.229	0.225
	Age 50-54, Female	0.565	0.459	0.364	0.281	0.276
	Age 55-59, Female	0.569	0.461	0.366	0.283	0.278
	Age 60-64, Female	0.616	0.505	0.405	0.320	0.315
Diagnosis Factors						
HCC001	HIV/AIDS	1.372	1.241	1.148	1.066	1.062
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	9.748	9.526	9.394	9.265	9.261
HCC003	Central Nervous System Infections, Except Viral Meningitis	8.571	8.427	8.323	8.202	8.195
HCC004	Viral or Unspecified Meningitis	8.571	8.427	8.323	8.202	8.195
HCC006	Opportunistic Infections	8.171	8.081	7.987	7.849	7.840
HCC008	Metastatic Cancer	24.079	23.695	23.536	23.460	23.461
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	14.384	14.117	13.991	13.897	13.896
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	5.887	5.722	5.626	5.532	5.528
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.865	3.677	3.547	3.410	3.404
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.559	2.414	2.305	2.185	2.180
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.134	1.018	0.893	0.744	0.735
HCC018	Pancreas Transplant Status	0.875	0.813	0.806	1.044	1.021
HCC019	Diabetes with Acute Complications	0.385	0.323	0.262	0.202	0.198
HCC020	Diabetes with Chronic Complications	0.385	0.323	0.262	0.202	0.198
HCC021	Diabetes without Complication	0.385	0.323	0.262	0.202	0.198
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19-21	0.311	0.276	0.242	0.173	0.169
HCC023	Protein-Calorie Malnutrition	10.875	10.752	10.670	10.587	10.582
HCC026	Mucopolysaccharidosis	28.668	28.458	28.362	28.308	28.309

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HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC027	Lipidoses and Glycogenosis	28.668	28.458	28.362	28.308	28.309
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	7.531	7.405	7.319	7.244	7.242
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.328	1.224	1.125	1.007	1.001
HCC034	Liver Transplant Status/Complications	8.038	7.973	7.884	7.864	7.853
HCC035_1 ⁴⁷	Acute Liver Failure/Disease, Including Neonatal Hepatitis	7.063	6.914	6.849	6.800	6.798
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	2.906	2.734	2.630	2.520	2.516
HCC036	Cirrhosis of Liver	1.283	1.180	1.078	0.946	0.938
HCC037_1	Chronic Viral Hepatitis C	0.830	0.731	0.637	0.529	0.523
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.830	0.731	0.637	0.529	0.523
HCC041	Intestine Transplant Status/Complications	23.291	23.157	23.033	22.817	22.812
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.657	11.449	11.339	11.253	11.250
HCC045	Intestinal Obstruction	4.859	4.672	4.585	4.484	4.482
HCC046	Chronic Pancreatitis	3.262	3.088	3.000	2.913	2.912
HCC047	Acute Pancreatitis	2.933	2.727	2.593	2.418	2.412
HCC048	Inflammatory Bowel Disease	0.820	0.731	0.626	0.488	0.479
HCC054	Necrotizing Fasciitis	8.872	8.708	8.632	8.596	8.595
HCC055	Bone/Joint/Muscle Infections/Necrosis	4.708	4.536	4.467	4.432	4.432
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	1.340	1.230	1.121	1.001	0.994
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.878	0.782	0.664	0.514	0.505
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.463	2.304	2.185	2.051	2.044
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.463	2.304	2.185	2.051	2.044
HCC063	Cleft Lip/Cleft Palate	1.676	1.544	1.437	1.309	1.303
HCC066	Hemophilia	69.981	69.651	69.503	69.435	69.435
HCC067	Myelodysplastic Syndromes and Myelofibrosis	13.285	13.162	13.096	13.039	13.036
HCC068	Aplastic Anemia	13.285	13.162	13.096	13.039	13.036
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	13.285	13.162	13.096	13.039	13.036
HCC070	Sickle Cell Anemia (Hb-SS)	2.395	2.283	2.191	2.082	2.077
HCC071	Beta Thalassemia Major	2.395	2.283	2.191	2.082	2.077
HCC073	Combined and Other Severe Immunodeficiencies	4.039	3.936	3.888	3.840	3.839
HCC074	Disorders of the Immune Mechanism	4.039	3.936	3.888	3.840	3.839
HCC075	Coagulation Defects and Other Specified Hematological Disorders	1.763	1.672	1.594	1.499	1.495

⁴⁷ HCC numbers that appear with an underscore in this document will appear without the underscore in the DIY software. For example, HCC 35_1 in this table will appear as HCC 351 in the DIY software.

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HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC081	Drug Use with Psychotic Complications	2.438	2.264	2.108	1.897	1.885
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.438	2.264	2.108	1.897	1.885
HCC083	Alcohol Use with Psychotic Complications	1.296	1.171	1.057	0.911	0.903
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.296	1.171	1.057	0.911	0.903
HCC087_1	Schizophrenia	2.445	2.260	2.121	1.961	1.954
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	2.372	2.199	2.067	1.894	1.886
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	1.271	1.141	1.008	0.838	0.829
HCC090	Personality Disorders	0.856	0.742	0.606	0.446	0.435
HCC094	Anorexia/Bulimia Nervosa	2.223	2.099	1.993	1.875	1.869
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	8.930	8.904	8.869	8.785	8.778
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.051	0.965	0.880	0.783	0.777
HCC102	Autistic Disorder	0.974	0.865	0.741	0.602	0.593
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	0.856	0.742	0.606	0.446	0.435
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	10.321	10.159	10.050	9.940	9.936
HCC107	Quadriplegia	10.321	10.159	10.050	9.940	9.936
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	7.300	7.190	7.148	7.079	7.076
HCC109	Paraplegia	7.300	7.190	7.148	7.079	7.076
HCC110	Spinal Cord Disorders/Injuries	5.109	4.928	4.832	4.737	4.734
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.983	3.791	3.637	3.454	3.445
HCC112	Quadriplegic Cerebral Palsy	2.457	2.306	2.196	2.073	2.070
HCC113	Cerebral Palsy, Except Quadriplegic	0.911	0.825	0.739	0.628	0.621
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.633	1.516	1.406	1.273	1.266
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.117	5.042	5.019	4.999	4.999
HCC117	Muscular Dystrophy	1.717	1.593	1.473	1.307	1.298
HCC118	Multiple Sclerosis	3.304	3.144	3.019	2.877	2.870
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	1.717	1.593	1.473	1.307	1.298
HCC120	Seizure Disorders and Convulsions	1.262	1.142	1.028	0.887	0.879
HCC121	Hydrocephalus	10.147	10.050	9.987	9.914	9.910

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HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC122	Coma, Brain Compression/Anoxic Damage	10.005	9.852	9.745	9.624	9.618
HCC123	Narcolepsy and Cataplexy	5.856	5.690	5.554	5.405	5.397
HCC125	Respirator Dependence/Tracheostomy Status	21.425	21.213	21.080	20.954	20.949
HCC126	Respiratory Arrest	8.941	8.754	8.635	8.523	8.520
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	8.941	8.754	8.635	8.523	8.520
HCC128	Heart Assistive Device/Artificial Heart	21.035	20.838	20.709	20.586	20.580
HCC129	Heart Transplant Status/Complications	21.035	20.838	20.709	20.586	20.580
HCC130	Heart Failure	2.046	1.947	1.874	1.792	1.788
HCC131	Acute Myocardial Infarction	6.142	5.902	5.813	5.777	5.781
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.704	4.470	4.361	4.250	4.250
HCC135	Heart Infection/Inflammation, Except Rheumatic	8.866	8.749	8.645	8.507	8.499
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	1.910	1.809	1.715	1.613	1.608
HCC138	Major Congenital Heart/Circulatory Disorders	1.910	1.809	1.715	1.613	1.608
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.910	1.809	1.715	1.613	1.608
HCC142	Specified Heart Arrhythmias	1.838	1.717	1.608	1.473	1.469
HCC145	Intracranial Hemorrhage	11.065	10.884	10.774	10.662	10.658
HCC146	Ischemic or Unspecified Stroke	1.590	1.463	1.368	1.236	1.231
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.570	2.429	2.321	2.184	2.178
HCC150	Hemiplegia/Hemiparesis	3.409	3.301	3.271	3.263	3.266
HCC151	Monoplegia, Other Paralytic Syndromes	2.405	2.286	2.199	2.086	2.081
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	7.875	7.759	7.732	7.746	7.750
HCC154	Vascular Disease with Complications	5.620	5.504	5.463	5.427	5.427
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	7.977	7.859	7.751	7.617	7.608
HCC158	Lung Transplant Status/Complications	12.435	12.247	12.124	12.008	11.999
HCC159	Cystic Fibrosis	5.177	5.040	4.976	4.910	4.908
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.824	0.726	0.617	0.488	0.481
HCC161_1	Severe Asthma	0.824	0.726	0.617	0.488	0.481
HCC161_2	Asthma, Except Severe	0.824	0.726	0.617	0.488	0.481
HCC162	Fibrosis of Lung and Other Lung Disorders	1.742	1.631	1.532	1.403	1.396
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	7.455	7.417	7.378	7.350	7.349
HCC174	Exudative Macular Degeneration	1.438	1.298	1.167	0.991	0.982

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HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC183	Kidney Transplant Status/Complications	8.681	8.609	8.503	8.269	8.263
HCC184	End Stage Renal Disease	22.696	22.390	22.310	22.358	22.400
HCC187	Chronic Kidney Disease, Stage 5	0.863	0.794	0.736	0.668	0.665
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.863	0.794	0.736	0.668	0.665
HCC203	Ectopic and Molar Pregnancy	2.155	1.952	1.753	1.433	1.416
HCC204	Miscarriage with Complications	0.924	0.813	0.657	0.430	0.413
HCC205	Miscarriage with No or Minor Complications	0.924	0.813	0.657	0.430	0.413
HCC207	Pregnancy with Delivery with Major Complications	4.064	3.783	3.551	3.135	3.118
HCC208	Pregnancy with Delivery with Complications	4.064	3.783	3.551	3.135	3.118
HCC209	Pregnancy with Delivery with No or Minor Complications	2.847	2.639	2.414	1.955	1.928
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	1.280	1.141	0.959	0.726	0.711
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.879	0.766	0.607	0.438	0.427
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.352	0.280	0.190	0.123	0.119
HCC217	Chronic Ulcer of Skin, Except Pressure	1.533	1.420	1.330	1.220	1.215
HCC218	Extensive Third Degree Burns	23.966	23.738	23.617	23.538	23.536
HCC219	Major Skin Burn or Condition	2.364	2.241	2.145	2.041	2.036
HCC223	Severe Head Injury	17.030	16.895	16.771	16.632	16.624
HCC226	Hip and Pelvic Fractures	8.337	8.132	8.048	7.995	7.996
HCC228	Vertebral Fractures without Spinal Cord Injury	4.358	4.194	4.090	3.962	3.956
HCC234	Traumatic Amputations and Amputation Complications	4.952	4.795	4.736	4.696	4.697
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	22.648	22.602	22.510	22.387	22.377
HCC253	Artificial Openings for Feeding or Elimination	6.513	6.413	6.376	6.352	6.352
HCC254	Amputation Status, Upper Limb or Lower Limb	1.806	1.671	1.574	1.456	1.451
Interacted HCC Counts Factors						
	Severe illness, 1 payment HCC	-6.091	-6.125	-6.181	-6.267	-6.271
	Severe illness, 2 payment HCCs	-5.758	-5.804	-5.824	-5.883	-5.886
	Severe illness, 3 payment HCCs	-4.600	-4.607	-4.526	-4.404	-4.393
	Severe illness, 4 payment HCCs	-3.648	-3.586	-3.415	-3.138	-3.118
	Severe illness, 5 payment HCCs	-2.965	-2.815	-2.554	-2.137	-2.110
	Severe illness, 6 payment HCCs	-2.718	-2.456	-2.103	-1.561	-1.528
	Severe illness, 7 payment HCCs	-1.848	-1.445	-0.987	-0.319	-0.281
	Severe illness, 8 payment HCCs	-1.328	-0.842	-0.328	0.405	0.446
	Severe illness, 9 payment HCCs	0.191	0.836	1.458	2.310	2.355
	Severe illness, 10 or more payment HCCs	8.579	9.578	10.431	11.526	11.579

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	Transplant severe illness, 4 payment HCCs	3.559	3.502	3.483	3.483	3.487
	Transplant severe illness, 5 payment HCCs	7.420	7.365	7.353	7.363	7.368
	Transplant severe illness, 6 payment HCCs	12.674	12.625	12.622	12.645	12.652
	Transplant severe illness, 7 payment HCCs	18.766	18.696	18.688	18.707	18.715
	Transplant severe illness, 8 or more payment HCCs	33.796	33.788	33.829	33.905	33.916
Enrollment Duration Factors						
	Enrolled for 1 month, at least one payment HCC	9.287	7.981	6.876	5.547	5.462
	Enrolled for 2 months, at least one payment HCC	3.618	2.896	2.336	1.799	1.768
	Enrolled for 3 months, at least one payment HCC	2.088	1.641	1.282	0.965	0.947
	Enrolled for 4 months, at least one payment HCC	1.105	0.816	0.572	0.376	0.366
	Enrolled for 5 months, at least one payment HCC	0.770	0.563	0.380	0.235	0.226
	Enrolled for 6 months, at least one payment HCC	0.499	0.351	0.215	0.123	0.120
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	8.499	7.914	7.511	7.007	6.990
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	6.593	6.146	5.958	5.830	5.835
RXC 03	Antiarrhythmics	0.117	0.107	0.103	0.069	0.050
RXC 04	Phosphate Binders	2.009	2.016	2.007	1.953	1.880
RXC 05	Inflammatory Bowel Disease Agents	1.519	1.374	1.206	0.941	0.924
RXC 06	Insulin	1.227	1.005	0.762	0.500	0.483
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.671	0.570	0.463	0.346	0.339
RXC 08	Multiple Sclerosis Agents	23.184	22.318	21.874	21.467	21.466
RXC 09	Immune Suppressants and Immunomodulators	12.774	12.347	12.139	11.992	11.988
RXC 10	Cystic Fibrosis Agents	17.803	17.474	17.358	17.299	17.304
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001	2.316	2.503	2.790	3.284	3.310
RXC 02 x HCC 37_1, 36_035_s_34	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.678	-0.555	-0.433	-0.264	-0.256
RXC_03_x_HCC142	Additional effect for enrollees with RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC_04_x_HCC184_183_187_188	Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188)	0.000	0.000	0.000	0.000	0.000

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RXC_05_x_HCC048_041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041)	-0.381	-0.341	-0.282	-0.235	-0.231
RXC_06_x_HCC018_019_020_021	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021)	0.560	0.647	0.761	0.781	0.784
RXC_07_x_HCC018_019_020_021	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021)	-0.204	-0.151	-0.117	-0.134	-0.136
RXC_08_x_HCC118	Additional effect for enrollees with RXC 08 and HCC 118	-0.539	-0.056	0.316	0.813	0.827
RXC_09_x_HCC056_057_and_048_041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057)	0.693	0.764	0.827	0.909	0.915
RXC_09_x_HCC056	Additional effect for enrollees with RXC 09 and HCC 056	0.757	0.824	0.959	1.153	1.166
RXC_09_x_HCC057	Additional effect for enrollees with RXC 09 and HCC 057	-0.878	-0.782	-0.664	-0.514	-0.505
RXC_09_x_HCC048_041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041)	3.331	3.335	3.439	3.648	3.664
RXC_10_x_HCC159_158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	46.175	46.175	46.180	46.278	46.282

TABLE 2: Proposed Child Risk Adjustment Model Factors for 2022 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2-4, Male	0.267	0.201	0.153	0.116	0.113
Age 5-9, Male	0.192	0.135	0.097	0.070	0.068
Age 10-14, Male	0.223	0.164	0.120	0.093	0.091
Age 15-20, Male	0.271	0.208	0.156	0.117	0.115
Age 2-4, Female	0.221	0.163	0.126	0.100	0.098
Age 5-9, Female	0.163	0.112	0.080	0.060	0.058
Age 10-14, Female	0.212	0.155	0.116	0.091	0.089
Age 15-20, Female	0.336	0.258	0.195	0.147	0.144
Diagnosis Factors					
HIV/AIDS	5.961	5.577	5.357	5.139	5.133
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	16.453	16.237	16.111	15.962	15.955
Central Nervous System Infections, Except Viral Meningitis	14.787	14.627	14.548	14.496	14.493
Viral or Unspecified Meningitis	12.890	12.778	12.672	12.532	12.528
Opportunistic Infections	18.089	18.031	17.967	17.889	17.881
Metastatic Cancer	33.956	33.679	33.535	33.432	33.430

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Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.363	9.131	8.985	8.839	8.833
Non-Hodgkin Lymphomas and Other Cancers and Tumors	7.171	6.961	6.817	6.657	6.649
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.764	3.582	3.413	3.207	3.192
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.764	3.582	3.413	3.207	3.192
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.098	0.968	0.841	0.678	0.675
Pancreas Transplant Status	14.723	14.594	14.579	14.489	14.535
Diabetes with Acute Complications	2.527	2.261	2.012	1.649	1.685
Diabetes with Chronic Complications	2.527	2.261	2.012	1.649	1.685
Diabetes without Complication	2.527	2.261	2.012	1.649	1.685
Protein-Calorie Malnutrition	18.838	18.721	18.666	18.639	18.634
Mucopolysaccharidosis	39.199	38.932	38.800	38.702	38.699
Lipidoses and Glycogenosis	39.199	38.932	38.800	38.702	38.699
Congenital Metabolic Disorders, Not Elsewhere Classified	5.406	5.282	5.186	5.086	5.081
Amyloidosis, Porphyria, and Other Metabolic Disorders	5.406	5.282	5.186	5.086	5.081
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.355	6.124	5.993	5.896	5.892
Liver Transplant Status/Complications	14.723	14.594	14.579	14.489	14.535
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.829	11.676	11.608	11.560	11.558
Chronic Liver Failure/End-Stage Liver Disorders	11.044	10.886	10.801	10.710	10.707
Cirrhosis of Liver	3.402	3.311	3.228	3.084	3.080
Chronic Viral Hepatitis C	2.086	1.923	1.815	1.753	1.754
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.755	0.637	0.542	0.431	0.422
Intestine Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	18.426	18.175	18.075	18.044	18.045
Intestinal Obstruction	3.900	3.703	3.548	3.358	3.348
Chronic Pancreatitis	10.399	10.199	10.109	10.054	10.048
Acute Pancreatitis	5.156	4.921	4.757	4.537	4.524
Inflammatory Bowel Disease	9.409	9.061	8.862	8.668	8.661
Necrotizing Fasciitis	3.086	2.881	2.730	2.580	2.572
Bone/Joint/Muscle Infections/Necrosis	3.086	2.881	2.730	2.580	2.572
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.935	4.699	4.541	4.399	4.393
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.271	1.141	1.004	0.853	0.841
Osteogenesis Imperfecta and Other Osteodystrophies	1.247	1.140	1.045	0.942	0.936
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.247	1.140	1.045	0.942	0.936

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Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Cleft Lip/Cleft Palate	1.394	1.228	1.039	0.852	0.840
Hemophilia	71.996	71.523	71.295	71.146	71.145
Myelodysplastic Syndromes and Myelofibrosis	13.679	13.505	13.401	13.301	13.296
Aplastic Anemia	13.679	13.505	13.401	13.301	13.296
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	13.679	13.505	13.401	13.301	13.296
Sickle Cell Anemia (Hb-SS)	5.557	5.356	5.213	5.061	5.056
Beta Thalassemia Major	5.557	5.356	5.213	5.061	5.056
Combined and Other Severe Immunodeficiencies	4.311	4.157	4.042	3.914	3.904
Disorders of the Immune Mechanism	4.311	4.157	4.042	3.914	3.904
Coagulation Defects and Other Specified Hematological Disorders	3.342	3.212	3.096	2.963	2.955
Drug Use with Psychotic Complications	2.473	2.289	2.136	1.945	1.934
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.473	2.289	2.136	1.945	1.934
Alcohol Use with Psychotic Complications	1.387	1.245	1.107	0.925	0.913
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.387	1.245	1.107	0.925	0.913
Schizophrenia	4.545	4.264	4.068	3.841	3.830
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.056	2.824	2.627	2.376	2.362
Major Depressive Disorder, Severe, and Bipolar Disorders	2.587	2.379	2.188	1.947	1.935
Personality Disorders	0.612	0.515	0.397	0.272	0.265
Anorexia/Bulimia Nervosa	2.511	2.348	2.211	2.071	2.063
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	12.839	12.760	12.707	12.664	12.658
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.547	1.401	1.266	1.082	1.063
Autistic Disorder	2.587	2.379	2.188	1.947	1.935
Pervasive Developmental Disorders, Except Autistic Disorder	0.612	0.515	0.404	0.304	0.299
Traumatic Complete Lesion Cervical Spinal Cord	9.556	9.348	9.228	9.121	9.119
Quadriplegia	9.556	9.348	9.228	9.121	9.119
Traumatic Complete Lesion Dorsal Spinal Cord	8.665	8.452	8.339	8.216	8.212
Paraplegia	8.665	8.452	8.339	8.216	8.212
Spinal Cord Disorders/Injuries	3.428	3.241	3.094	2.912	2.898
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	32.864	32.642	32.500	32.372	32.367
Quadriplegic Cerebral Palsy	3.270	3.108	3.041	3.010	3.014
Cerebral Palsy, Except Quadriplegic	1.319	1.156	1.018	0.836	0.823
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.890	1.769	1.676	1.566	1.559
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.947	9.789	9.713	9.665	9.664

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Muscular Dystrophy	4.361	4.165	3.981	3.767	3.751
Multiple Sclerosis	12.642	12.278	12.119	12.017	12.015
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	4.361	4.165	3.981	3.767	3.751
Seizure Disorders and Convulsions	1.619	1.477	1.313	1.130	1.119
Hydrocephalus	12.782	12.747	12.714	12.712	12.717
Coma, Brain Compression/Anoxic Damage	12.827	12.750	12.666	12.598	12.595
Narcolepsy and Cataplexy	5.101	4.922	4.761	4.563	4.549
Respirator Dependence/Tracheostomy Status	30.364	30.125	30.016	29.935	29.930
Respiratory Arrest	15.552	15.311	15.186	15.055	15.047
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	15.552	15.311	15.186	15.055	15.047
Heart Assistive Device/Artificial Heart	16.105	16.018	15.984	15.983	15.990
Heart Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Heart Failure	4.636	4.513	4.419	4.297	4.290
Acute Myocardial Infarction	1.745	1.578	1.435	1.332	1.336
Unstable Angina and Other Acute Ischemic Heart Disease	1.745	1.578	1.435	1.332	1.336
Heart Infection/Inflammation, Except Rheumatic	15.639	15.486	15.366	15.212	15.200
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	3.058	2.842	2.650	2.438	2.418
Major Congenital Heart/Circulatory Disorders	0.999	0.865	0.721	0.605	0.596
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.747	0.646	0.546	0.467	0.461
Specified Heart Arrhythmias	2.745	2.562	2.384	2.227	2.217
Intracranial Hemorrhage	14.578	14.462	14.366	14.264	14.261
Ischemic or Unspecified Stroke	1.440	1.361	1.277	1.198	1.197
Cerebral Aneurysm and Arteriovenous Malformation	2.668	2.517	2.365	2.101	2.085
Hemiplegia/Hemiparesis	4.576	4.442	4.359	4.245	4.236
Monoplegia, Other Paralytic Syndromes	3.018	2.871	2.758	2.618	2.610
Atherosclerosis of the Extremities with Ulceration or Gangrene	11.183	10.985	10.861	10.737	10.734
Vascular Disease with Complications	6.308	6.163	6.068	5.980	5.976
Pulmonary Embolism and Deep Vein Thrombosis	20.304	20.162	20.087	20.027	20.021
Lung Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Cystic Fibrosis	48.367	47.908	47.701	47.590	47.584
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	2.003	1.844	1.699	1.518	1.508
Severe Asthma	1.185	1.018	0.827	0.633	0.622
Asthma, Except Severe	0.382	0.297	0.203	0.123	0.119
Fibrosis of Lung and Other Lung Disorders	1.185	1.018	0.827	0.633	0.622
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	12.351	12.306	12.275	12.298	12.298
Kidney Transplant Status/Complications	14.723	14.594	14.579	14.489	14.535
End Stage Renal Disease	37.215	37.008	36.936	36.933	36.936
Chronic Kidney Disease, Stage 5	3.859	3.728	3.618	3.482	3.475
Chronic Kidney Disease, Severe (Stage 4)	3.859	3.728	3.618	3.482	3.475

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Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Ectopic and Molar Pregnancy	2.067	1.842	1.626	1.295	1.279
Miscarriage with Complications	0.912	0.778	0.597	0.346	0.329
Miscarriage with No or Minor Complications	0.912	0.778	0.597	0.346	0.329
Pregnancy with Delivery with Major Complications	3.751	3.463	3.195	2.691	2.661
Pregnancy with Delivery with Complications	3.751	3.463	3.195	2.691	2.661
Pregnancy with Delivery with No or Minor Complications	2.650	2.428	2.165	1.661	1.624
(Ongoing) Pregnancy without Delivery with Major Complications	0.977	0.822	0.619	0.388	0.374
(Ongoing) Pregnancy without Delivery with Complications	0.977	0.822	0.619	0.388	0.374
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.485	0.378	0.252	0.147	0.142
Chronic Ulcer of Skin, Except Pressure	1.504	1.383	1.263	1.141	1.135
Extensive Third Degree Burns	20.205	19.995	19.885	19.821	19.818
Major Skin Burn or Condition	1.867	1.723	1.600	1.455	1.447
Severe Head Injury	20.205	19.995	19.885	19.821	19.818
Hip and Pelvic Fractures	3.665	3.439	3.263	3.101	3.095
Vertebral Fractures without Spinal Cord Injury	3.353	3.148	2.963	2.739	2.726
Traumatic Amputations and Amputation Complications	3.936	3.723	3.565	3.352	3.338
Stem Cell, Including Bone Marrow, Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Artificial Openings for Feeding or Elimination	7.197	7.036	6.985	6.947	6.949
Amputation Status, Upper Limb or Lower Limb	3.936	3.723	3.565	3.352	3.338
Interacted HCC Counts Factors					
Severe illness, 1 payment HCC	-11.292	-11.358	-11.441	-11.583	-11.595
Severe illness, 2 payment HCCs	-11.146	-11.138	-11.169	-11.269	-11.257
Severe illness, 3 payment HCCs	-9.366	-9.392	-9.391	-9.345	-9.341
Severe illness, 4 payment HCCs	-8.988	-8.982	-8.891	-8.710	-8.694
Severe illness, 5 payment HCCs	-7.182	-7.013	-6.744	-6.377	-6.349
Severe illness, 6 or 7 payment HCCs	-1.583	-1.238	-0.827	-0.285	-0.249
Severe illness, 8 or more payment HCCs	18.271	19.100	19.861	20.772	20.830
Transplant severe illness, 4 or more payment HCCs	17.085	17.121	17.096	17.068	17.040

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TABLE 3: HCCs Selected for the Proposed HCC Interacted Counts Variables for the Adult and Child Models Beginning with the 2022 Benefit Year

Payment HCC	Severity Illness Indicator	Transplant Indicator ⁴⁸
HCC 2 Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	X	
HCC 3 Central Nervous System Infections, Except Viral Meningitis	X	
HCC 4 Viral or Unspecified Meningitis	X	
HCC 6 Opportunistic Infections	X	
HCC 23 Protein-Calorie Malnutrition	X	
HCC 34 Liver Transplant Status/Complications	X	X
HCC 41 Intestine Transplant Status/Complications	X	X
HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	X	
HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	X	
HCC 121 Hydrocephalus	X	
HCC 122 Coma, Brain Compression/Anoxic Damage	X	
HCC 125 Respirator Dependence/Tracheostomy Status	X	
HCC 135 Heart Infection/Inflammation, Except Rheumatic	X	
HCC 145 Intracranial Hemorrhage	X	
HCC 156 Pulmonary Embolism and Deep Vein Thrombosis	X	
HCC 158 Lung Transplant Status/Complications	X	X
HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	X	
HCC 183 Kidney Transplant Status/Complications	X	X
HCC 218 Extensive Third Degree Burns	X	
HCC 223 Severe Head Injury	X	
HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications	X	X
G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes)	X	
G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications)	X	X

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

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	228.512	227.071	226.378	225.986	225.985
Extremely Immature * Severity Level 4	143.939	142.392	141.573	140.987	140.976
Extremely Immature * Severity Level 3	32.833	31.691	31.019	30.471	30.451
Extremely Immature * Severity Level 2	32.833	31.691	31.019	30.471	30.451
Extremely Immature * Severity Level 1 (Lowest)	32.833	31.691	31.019	30.471	30.451
Immature * Severity Level 5 (Highest)	132.085	130.648	129.935	129.486	129.480

⁴⁸ We note that one transplant HCC (HCC 18 Pancreas Transplant) is not included on this list. HCC 18 had a much lower coefficient than any of the other transplant HCCs in the adult models and was not underpredicted by the models. However, we are considering whether we should add HCC 18 to the interacted HCC counts model specifications.

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Group	Platinum	Gold	Silver	Bronze	Catastrophic
Immature * Severity Level 4	69.277	67.949	67.232	66.691	66.675
Immature * Severity Level 3	32.833	31.691	31.019	30.471	30.451
Immature * Severity Level 2	28.029	26.918	26.246	25.672	25.650
Immature * Severity Level 1 (Lowest)	25.390	24.329	23.673	23.095	23.072
Premature/Multiples * Severity Level 5 (Highest)	109.526	108.295	107.661	107.236	107.227
Premature/Multiples * Severity Level 4	28.669	27.553	26.884	26.312	26.294
Premature/Multiples * Severity Level 3	14.196	13.345	12.721	12.054	12.022
Premature/Multiples * Severity Level 2	8.093	7.463	6.897	6.212	6.173
Premature/Multiples * Severity Level 1 (Lowest)	5.774	5.254	4.759	4.243	4.214
Term * Severity Level 5 (Highest)	82.605	81.544	80.955	80.511	80.498
Term * Severity Level 4	15.976	15.156	14.564	13.941	13.916
Term * Severity Level 3	6.071	5.541	5.020	4.437	4.404
Term * Severity Level 2	3.634	3.194	2.696	2.144	2.111
Term * Severity Level 1 (Lowest)	1.853	1.534	1.163	0.917	0.905
Age1 * Severity Level 5 (Highest)	63.472	62.803	62.434	62.174	62.167
Age1 * Severity Level 4	12.474	12.010	11.689	11.375	11.362
Age1 * Severity Level 3	3.139	2.867	2.637	2.419	2.408
Age1 * Severity Level 2	1.980	1.751	1.529	1.304	1.291
Age1 * Severity Level 1 (Lowest)	0.573	0.496	0.442	0.403	0.401
Age 0 Male	0.608	0.566	0.525	0.459	0.455
Age 1 Male	0.106	0.090	0.072	0.051	0.050

TABLE 5: HHS HCCs Included in Infant Model Maturity Categories

Maturity Category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birth weight < 500 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500-749 Grams
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750-999 Grams
Immature	Premature Newborns, Including Birth weight 1000-1499 Grams
Immature	Premature Newborns, Including Birth weight 1500-1999 Grams
Premature/Multiples	Premature Newborns, Including Birth weight 2000-2499 Grams
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight
Age 1	All age 1 infants

TABLE 6: HHS HCCs Included in Infant Model Severity Categories

Severity Category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant Status/Complications
Severity Level 5	Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status/Complications

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

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Severity Category	HCC/Description
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

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Severity Category	HCC/Description
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

f. 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 2022 benefit year, to maintain stability and certainty for issuers, we are proposing to maintain the CSR factors finalized in the 2019, 2020, and 2021 Payment Notices.⁴⁹ See Table 7.

Consistent with the approach finalized in the 2017 Payment Notice,⁵⁰ we propose to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent.

We seek comment on these proposals.

⁴⁹ See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; and 85 FR 29164 at 29190.

⁵⁰ See 81 FR 12203 at 12228.

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TABLE 7: Cost-Sharing Reduction Adjustment

Household Income	Plan AV	Induced Utilization Factor
Silver Plan Variant Recipients		
100-150% of Federal Poverty Line (FPL)	Plan Variation 94%	1.12
150-200% of FPL	Plan Variation 87%	1.12
200-250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

g. Model Performance Statistics

To evaluate risk adjustment model performance, we examined each model's R-squared statistic and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratios are in the range of published estimates for concurrent risk adjustment models.⁵¹ We note that the proposed model specification updates generally demonstrate improvements in R-squared as well as predictive ratios. Because we propose to blend the coefficients from separately solved models

⁵¹ Hileman, Geof and Spenser Steele. "Accuracy of Claims-Based Risk Scoring Models." Society of Actuaries. October 2016.

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based on the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 8.

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

R-Squared Statistic			
Models	2016 Enrollee-level EDGE Data	2017 Enrollee-level EDGE Data	2018 Enrollee-level EDGE Data
Platinum Adult	0.4488	0.4465	0.4319
Gold Adult	0.4439	0.4412	0.4265
Silver Adult	0.4406	0.4376	0.4227
Bronze Adult	0.4367	0.4335	0.4182
Catastrophic Adult	0.4364	0.4332	0.4179
Platinum Child	0.3375	0.3517	0.3535
Gold Child	0.3348	0.3488	0.3506
Silver Child	0.3325	0.3463	0.3481
Bronze Child	0.3294	0.3432	0.3449
Catastrophic Child	0.3292	0.3430	0.3447
Platinum Infant	0.3268	0.3272	0.2888
Gold Infant	0.3238	0.3242	0.2855
Silver Infant	0.3218	0.3220	0.2833
Bronze Infant	0.3195	0.3197	0.2810
Catastrophic Infant	0.3194	0.3196	0.2809

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

On August 4, 2020, HHS adopted temporary policies of relaxed enforcement for the premium rules set forth at 45 CFR 147.102, 155.200(f)(4), 155.400(e) and (g), 155.706(b)(6)(1)(A), 156.80(d), 156.210(a), and 156.286(a)(2) through (4) to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage.⁵² HHS provided this flexibility with the intent of supporting continuity of coverage for individuals, families, and small employers who may

⁵² "Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency," August 4, 2020. <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

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struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE.

In prior rulemaking,⁵³ CMS finalized the calculation of plan average premium in the risk adjustment state payment transfer formula as equal to the actual premiums charged to plan enrollees, weighted by the number of months enrolled, and finalized the calculation of the state average premium as equal to the average of individual plan average premiums, weighted by each plan's share of statewide enrollment in the risk pool market, based on billable member months. In the interim final rule on COVID-19, HHS set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year. In this rule, we propose how HHS would treat temporary premium credits provided for purposes of applying the state payment transfer formula for the 2021 benefit year and beyond should HHS adopt a similar relaxed enforcement stance and permit such temporary premium credits in future benefit years during a PHE declared by the Secretary of HHS (declared PHE).⁵⁴ For states where issuers of risk adjustment covered plans provide temporary premium credits when permitted by HHS, the plan average premium and statewide average premium used in the state payment transfer formula would be calculated using issuers' adjusted premium amounts. Thus, the actual premiums billed to plan enrollees would be the amounts used in the calculations under the state payment transfer formula. This is consistent with the general approach adopted in the interim final rule on COVID-19 for temporary premium credits in the 2020 benefit year.

We further propose that HHS would use adjusted plan premiums for all enrollees to whom the issuer has actually provided premium credits as a reduction to the applicable benefit

⁵³ 2014 Payment Notice final rule, 78 FR 15409. Also see the 2020 Payment Notice final rule, 84 FR 17454.

⁵⁴ The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: a) a disease or disorder presents a public health emergency; or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

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year premiums, when calculating transfers under the state payment transfer formula for the 2022 benefit year and beyond. This approach would also extend to the calculation of transfers under the state payment transfer formula in states that receive approval for a request to reduce transfers under § 153.320(d) – that is, the lower actual premiums for which plan enrollees would be responsible would be the amounts used in the calculations under the state payment transfer formula to reflect these temporary premium credits. As such, if an issuer in a state with an approved 50 percent small group market reduction request for a given benefit year chooses to provide temporary premium credits, the state average premium will decrease, and HHS would apply the 50 percent transfer reduction to the lower PMPM payment or charge transfer amount calculated under the state payment transfer formula for that state’s small group market for that benefit year. As detailed further later in this preamble, we also propose that issuers providing these temporary premium credits must report the lower, actual premium amounts billed to plan enrollees to their respective EDGE servers. We believe that the applicable definitions of plan average premium and state average premium retain the meaning previously finalized by reflecting the actual monthly premium billed to enrollees. This proposal builds on lessons learned from the COVID-19 PHE and would establish a framework to recognize premium credits as a reduction in premium for purposes of the HHS-operated risk adjustment program in order to align risk adjustment charges and payments under the state payment transfer formula with flexibilities HHS may provide to issuers and states in future benefit years. This proposal would not change any other aspect of the state payment transfer formula or the method for calculating payments and charges under the HHS risk adjustment methodology (inclusive of the state payment transfer formula and high-cost risk pool parameters).

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

We propose to continue to use the HHS state payment transfer formula that was finalized in the 2021 Payment Notice.⁵⁵ Although the proposed HHS state payment transfer formula for the 2022 benefit year is unchanged from what was finalized for the previous benefit year, we are republishing it 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.⁵⁶ We also propose to apply this state payment transfer formula, including the administrative cost reduction, for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. If this policy is finalized as proposed, we would no longer republish these formulas in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed. To align with this proposal, we propose to update § 153.320(c) to replace the current language that refers to HHS specifying the applicable Federally certified risk adjustment methodology in the annual HHS notice of benefit and payment parameters for the applicable year to instead require HHS to specify the applicable Federally certified risk adjustment methodology in notice and comment rulemaking that is published in advance of the applicable benefit year.

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule.⁵⁷ In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.⁵⁸ This formula generally calculates the difference between the revenues required by a plan, based on the health

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

⁵⁶ *Ibid.*

⁵⁷ 77 FR 17220 at 17246.

⁵⁸ 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.

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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,⁵⁹ 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.⁶⁰

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

⁵⁹ 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).

⁶⁰ See the 2020 Payment Notice final rule for further details on why statewide average premium is the cost-scaling factor in the state payment transfer formula. See 84 FR 17454 at 17480 through 17484.

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

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 combination of metal level AV, allowable rating factor, induced demand factor, and geographic cost factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers under the state payment transfer formula are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment state payment transfer calculations.⁶¹ This resulting PMPM plan

⁶¹ 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.

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

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

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

Where:

s_i = plan i 's share of statewide enrollment in the market in the risk pool;

P_i = average premium per member month of plan i .

We previously adopted a 14 percent administrative cost reduction to the statewide average premium⁶² and propose maintaining it for the 2022 benefit year and beyond, unless amended through notice-and-comment rulemaking.

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,⁶³ 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

⁶² See 84 FR 17454 at 17486.

⁶³ 84 FR 17466 through 17468.

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changes to the high-cost risk pool parameters as part of this proposed rule; therefore, we would maintain the threshold of \$1 million and coinsurance rate of 60 percent for the 2022 benefit year.

The high-cost risk pool adjustment amount is added to the state payment transfer formula to account for: (1) the payment term, representing the portion of costs above the threshold reimbursed to the issuer for high-cost risk pool payments (HRP_i), if applicable; and (2) the charge term, representing a percentage of premium adjustment, which is the product of the high-cost risk pool adjustment factor ($HRPC_m$) for the respective national high-cost risk pool m (one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market), and the plan's total premiums (TP_i). For this calculation, we use a percent of premium adjustment factor that is applied to each plan's total premium amount.

The total plan transfers for a given benefit year are calculated as the product of the plan's PMPM transfer amount (T_i) multiplied by the plan's billable member months (M_i), plus the high-cost risk pool adjustments. The total plan transfer (payment or charge) amounts under the HHS risk adjustment 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 ; and

TP_i = Plan i 's total premium amounts.

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We seek comment on the proposed HHS risk adjustment methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking.

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

In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment state transfers calculated by HHS under the state payment transfer formula, which is calibrated on a national dataset, for the state's individual (catastrophic or non-catastrophic risk pools), small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's markets.⁶⁴ We finalized that any requests received would be published in the applicable benefit year's proposed HHS notice of benefit and payment parameters, and the supporting evidence provided by the state in support of its request would be made available for public comment.⁶⁵

If the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence.⁶⁶ In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. If approved by HHS, state reduction requests will be applied to the plan PMPM payment or charge state

⁶⁴ 83 FR 16955 through 16960.

⁶⁵ 45 CFR 153.320(d)(3).

⁶⁶ See 45 CFR 153.320(d)(3).

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payment transfer amount (T_i in the state payment transfer formula above). For the 2020 and 2021 benefit years, the state of Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market and HHS approved both requests.⁶⁷

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

For the 2022 benefit year, HHS received a request to reduce risk adjustment state transfers for the Alabama individual and small group markets⁶⁸ by 50 percent.⁶⁹ Alabama's request states that the presence of a dominant carrier in the individual and small group markets precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the risk adjustment payment issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the individual and small group markets for the 2022 benefit year would not exceed 1 percent, the *de minimis* premium increase threshold set forth in § 153.320(d)(1)(iii) and (d)(4)(i)(B). We seek comment on this request to reduce risk adjustment state transfers in the Alabama individual and small group markets by 50 percent for the 2022 benefit year. The request and additional documentation submitted by Alabama is posted under the "State Flexibility Requests" heading at

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

⁶⁷ See 84 FR 17484 through 17485 and 85 FR 29193 through 29194.

⁶⁸ Alabama's individual market request is for a 50 percent reduction to risk adjustment transfers for its individual market non-catastrophic and catastrophic risk pools.

⁶⁹ Due to the COVID-19 PHE, we permitted states seeking to request a reduction in risk adjustment transfers for the 2022 benefit year an extension until September 1, 2020 to submit such request.

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b. Multi-Year State Flexibility Requests

We propose several amendments to § 153.320(d) to allow states to request a reduction to otherwise applicable risk adjustment state transfers calculated under the HHS-operated risk adjustment methodology for up to 3 years, beginning with the 2023 benefit year. Under current policy, states seeking to reduce risk adjustment state transfers in one or more of their market risk pools must submit a request to HHS each year describing the nature of their request and providing supporting documentation. HHS then reviews the request, sets forth the request in the applicable benefit year's HHS notice of benefit and payment parameters, and approves or denies it based on the evidence and analysis provided by the state in the request and the comments received to the applicable benefit year's proposed HHS notice of benefit and payment parameters. Pursuant to § 153.320(d)(1), states must submit this request annually, and HHS publishes state requests in the applicable benefit year's proposed and final annual HHS notice of benefit and payment parameters. Stakeholders have requested that HHS allow states to request multi-year risk adjustment flexibility reductions. We have continued to consider these comments and the potential benefits that multi-year requests could provide. HHS believes that there may be potential for multi-year risk adjustment flexibility requests to promote greater predictability and stability in state markets, as issuers would be able to consider the impact of a reduction to risk adjustment state transfers for their decisions on rating and participation in a state market beyond the upcoming benefit year, and the reduction in burden to states to complete this process annually. We note, however, that a potential increase in predictability and stability assumes that the request remains in effect for longer than 1 year.

In recognition of those comments, we propose to provide the flexibility for states to request a reduction to otherwise applicable risk adjustment state transfers calculated under the

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HHS-operated risk adjustment methodology's state payment transfer formula for up to 3 years beginning with the 2023 benefit year. At § 153.320, we propose to redesignate current paragraph (d)(2) as paragraph (d)(3) and create a new proposed paragraph (d)(2) to capture the ability for states to request a multi-year reduction in risk adjustment state transfers. Consistent with the existing requirements captured in § 153.320(d)(1)(i) through (iii), states making single or multi-year requests would be required to submit evidence and analysis as applicable that demonstrate the following for all years to which the request would apply: (1) state-specific factors that warrant an adjustment to more precisely account for differences in actuarial risk in the state market risk pool; (2) the percentage reductions to risk adjustment state transfers; and (3) a justification for the requested reduction in risk adjustment state transfers, or evidence demonstrating that the requested state transfer reduction would have *de minimis* impact on premiums, such that any necessary premium increase for issuers likely to receive reduced payments as a result of the requested reduction to risk adjustment state transfers would not exceed 1 percent for each year for which they are requesting a reduction to risk adjustment state transfers. This requirement for multi-year requests would be captured in new proposed § 153.320(d)(2)(i)(A). Additionally, for multi-year requests, the state would be required to confirm that it does not anticipate any significant changes to the impacted state market risk pools (for example, a material change in issuer participation in the insurance market, or significant changes in issuer market share or enrollment) for the benefit years included in its multi-year request. We propose to capture the new confirmation requirement applicable to multi-year requests at the new proposed § 153.320(d)(2)(i)(B).

As part of the new framework to permit multi-year requests, at § 153.320, we also propose to redesignate current paragraph (d)(4) as paragraph (d)(5) and to amend the reference in

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redesignated paragraph (d)(5)(i) to refer to redesignated paragraph (d)(5)(ii) and new proposed paragraph (d)(5)(iii). This new proposed paragraph would add language to provide HHS with authority to approve a shorter duration than that requested by the state if the supporting evidence and analysis provided by the state do not support the requested duration. This is similar to the existing authority in redesignated paragraph (d)(5)(ii) for HHS to approve a reduction amount that is lower than the amount requested by the state if the supporting evidence and analysis do not fully support the requested reduction amount. We believe this language is necessary and appropriate as it remains unclear if a state would have all of the necessary information to support a multi-year request at the time of initial application. Rather than adopt an approach that requires HHS to either approve all of the years requested by the state or none of them, the new proposed paragraph (d)(5)(iii) provides flexibility for HHS to approve the reduction for those years for which the supporting evidence and analysis support the requested reduction. We clarify that, if adopted as proposed, nothing in this new framework would prevent a state whose multi-year request was approved for a shorter duration to pursue a new, separate state flexibility request for the applicable benefit years that were not supported in the state's initial reduction request.

Recognizing that market conditions can change from one year to the next, we propose to reserve the right to require states with approved multi-year reduction requests to submit supplemental evidence in any subsequent year of the request after its initial approval, in the timeframe, form, and manner specified by HHS, when circumstances warrant. For example, after we have approved a multi-year request, if we become aware of an anticipated change in the state market risk pool to which the request applies (for example, new entrants or significant shifts in enrollment), we would ask the state to submit supplemental evidence demonstrating that it anticipates the applicable requirements regarding the impact of the reduction will still be met in

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the subsequent benefit years of the request. We would require the state to respond to our request for supplemental evidence within 30 calendar days of our request, and we would make such a request no later than February of the benefit year prior to the applicable benefit year (thus, we would request supplemental evidence from the state by February 2023 for the 2024 benefit year). We propose to create a new proposed § 153.320(d)(5)(iv) to capture this authority and to make a parallel amendment to add a new proposed paragraph (d)(2)(i)(C) to capture the state's obligation to respond to such requests. Codifying the ability for HHS to request that the state submit additional supplemental evidence after an initial approval of a multi-year state flexibility request is intended to address situations where a state may need to justify the continued application of the state flexibility request in the event that HHS projects a significant change in state market risk pool conditions during the term of the approved multi-year request based on review of newly available information or data.

HHS also proposes to retain the ability to terminate or modify the request during any one of the subsequent years of an approved multi-year request if additional data or new information does not support the continuation of the state's reduction request as written and the state has not provided sufficient supplemental evidence to rebut such data or information. HHS would inform the state department of insurance (DOI) of the termination or modification of its reduction request, require the state DOI to notify the impacted issuers within 15 calendar days of HHS's notice to the state, and publish information on the early termination or modification of a state's multi-year request on the CMS website⁷⁰ no later than March of the year preceding the applicable benefit year, or 30 days after receipt of information requested under new proposed

⁷⁰ Terminations of or modifications to state risk adjustment flexibility requests would be posted under the "Risk Adjustment State Flexibility Requests" heading on the CMS website at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs>.

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§ 153.320(d)(5)(iv), whichever is later. We propose to add paragraph (d)(5)(v) to capture HHS's authority to terminate or modify a previously approved multi-year request in these circumstances.

In addition, we propose to permit a state to withdraw its request before its natural expiration by notifying HHS of its requested withdrawal. A state would need to notify HHS of its intent to withdraw its request, in the form and manner specified by HHS, 60 calendar days prior to the state's deadline for rate setting for the applicable benefit year. HHS would require the state DOI to notify the impacted issuers at least 45 calendar days prior to the state's deadline for rate setting for the applicable benefit year, and would publish the information on the state's withdrawal request on the CMS website.⁷¹ We propose to add § 153.320(d)(2)(ii) to capture the requirements related to a state withdrawal of its approved multi-year reduction request prior to the natural expiration of the request.

We also propose to redesignate paragraph (d)(3) as paragraph (d)(4) and amend it to reflect that, beginning for the 2023 benefit year, all multi-year reduction requests would be published in the annual HHS notice of benefit and payment parameters that corresponds to the first year of the state's request (for example, a multi-year request applicable for the 2023 through 2025 benefit years would be published in the 2023 Payment Notice proposed rule). As noted above, we propose to publish information on any early terminations or modifications by HHS or state withdrawals of approved state multi-year reduction requests on the CMS website.

We seek comment on all aspects of the proposed framework to permit states to pursue multi-year state flexibility reduction requests under § 153.320(d) for up to 3 years, including the

⁷¹ State withdrawals of risk adjustment flexibility requests would be posted under the "Risk Adjustment State Flexibility Requests" heading on the CMS website at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs>.

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additional components that would apply to such requests, the timeframe for states to respond to HHS requests for supplemental data and evidence pertaining to multi-year reduction requests, and the proposal to only publish and solicit comments on multi-year reduction requests in the annual HHS notice of benefit and payment parameters that corresponds to the first year in which the flexibility is being requested.

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

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

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

We propose several amendments to § 153.410(d) to provide more clarity around the audit requirements for issuers of reinsurance-eligible plans. The proposed amendments explain the audit process, including what it means to properly comply with an audit and the consequences for failing to comply with audit requirements. We also propose to expand the oversight tools available to HHS to also provide authority for HHS to conduct compliance reviews of issuers of

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reinsurance-eligible plans to assess compliance with the applicable requirements of subparts E and H of part 153. These proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming reinsurance-eligible plans' compliance with the standards related to reinsurance payments in subparts E and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.⁷² For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we propose to codify in the amendments to § 153.410(d) would apply to all issuers of reinsurance-eligible plans. We believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random and targeted auditing of issuers of reinsurance-eligible plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue, but were not selected for audit in the year in question.

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

⁷² For further details, please see 78 FR 65100.

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We also propose to amend the existing introductory language in § 153.410(d) to remove the last sentence that discusses audit results and the accompanying requirements that an issuer must follow if an audit results in a finding of material weakness or significant deficiency. Additionally, as detailed further below, we propose to replace this with a new proposed framework that captures more details on the audit process and requirements for reinsurance-eligible plans. As amended, the introductory language at § 153.410(d) would reflect the authority for HHS, or its designee, to audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of subparts E and H of part 153. We also propose to move the existing introductory language in paragraph (d) requiring an issuer to ensure its relevant contractors, subcontractors, and agents cooperate with audits to a new proposed section, as detailed further below.

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

Further, we propose to amend § 153.410(d) to add a new paragraph (d)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (d)(2)(i), we propose to capture the requirement that currently appears in the introductory text of paragraph (d) for the issuer to ensure that its relevant contractors, subcontractors, and agents cooperate with any audit or compliance review under this section and

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also propose to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In new proposed paragraph (d)(2)(ii), we propose to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit. Specifically, such data would need to support the appropriateness and accuracy of the reinsurance payments under review as part of the audit. For example, HHS may request that issuers of reinsurance-eligible plans provide enrollment and claims files, plan reference data, and associated enrollee data sufficient to show that reinsurance payments received were appropriate. HHS encountered significant challenges in the 2014 benefit year audits when some issuers submitted data in a format that was not readable by HHS or its systems. To address this issue, we propose in new paragraph (d)(2)(ii) that issuers must submit audit data in the format and manner specified by HHS no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (d)(1)(i). For example, HHS may require issuers to submit the requested audit data via Electronic File Transfer. Additionally, under proposed paragraph (d)(2)(iii), HHS proposes to require that issuers respond to any audit notices, letters, request, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We believe that the proposed requirements in paragraph (d)(2) are necessary and appropriate to ensure the timely completion of audits and to prevent waste that results from repeated, fruitless attempts by HHS to obtain data.

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.410(d)(2)(ii) or (iii), as applicable, we propose to also add a new paragraph (d)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an

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extension, we propose to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraphs (d)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS' notice granting the extension of time.

Under § 153.410(d)(3), HHS proposes that it would share its preliminary audit findings with the issuer, and further proposes that the issuer would then have 30 calendar days to respond to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we propose under paragraph (d)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. We propose in new paragraph (d)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

HHS proposes to add a new paragraph § 153.410(d)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a

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

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.410(d), HHS proposes in paragraph (d)(5)(i) that HHS would notify the issuer of reinsurance payments received that the issuer has not adequately substantiated, and under new proposed paragraph (d)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated if the reinsurance debt is not paid. Therefore, the continued failure to comply with the audit requirements and provide the necessary information to substantiate the payments made could result in HHS recouping up to 100 percent of the reinsurance payments made to an issuer for the applicable benefit year(s) that are the subject of the audit if the reinsurance debt is not paid.

Reinsurance payment amounts recovered by HHS as a result of an audit under § 153.410(d) would be allocated, on a pro rata basis, as further payments to the U.S. Treasury under section 1341(b)(3)(B)(iv) of the PPACA and further reimbursement of administrative

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expenses related to operating the reinsurance program under section 1341(b)(3)(B)(ii) of the PPACA.⁷³

We seek comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, inquiries, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests.

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

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

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

⁷³ See the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30257 through 30259 (May 27, 2014).

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These proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming risk adjustment covered plans' compliance with the applicable requirements related to the risk adjustment program in subparts G and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.⁷⁴ For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we propose to codify in the amendments to § 153.620(c) would apply to all issuers of risk adjustment covered plans. We believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of issuers of risk adjustment covered plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. As noted above, at this time, we anticipate focusing our audit and compliance review activities under § 153.620(c) on ensuring compliance with requirements applicable to the high-cost risk pool payments under the HHS risk adjustment methodology.

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

⁷⁴ For further details, please see 78 FR 65100.

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and to note that we would conduct these compliance reviews consistent with the standards set forth in 45 CFR 156.715.

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

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

Further, HHS proposes to amend § 153.620(c) to add paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (c)(2)(i), we propose to capture the requirement that currently appears in the

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introductory text of paragraph (c) for the issuer to ensure that its relevant agents, contractors, and subcontractors cooperate with any audit or compliance review under this section and also propose to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In new proposed paragraph (c)(2)(ii), we propose to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit. Specifically, such data would need to support the appropriateness and accuracy of the risk adjustment transfers (including high-cost risk pool payments and charges) under review as part of the audit. For example, HHS may request that issuers of risk adjustment covered plans provide enrollment and claims files and plan reference data and associated enrollee data.

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

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.620(c)(2)(ii) or (iii), as applicable, we propose to also add a new paragraph (c)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an

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extension, we propose to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraph (c)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and the good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS' notice granting the extension of time.

Under § 153.620(c)(3), HHS proposes that it would share its preliminary audit findings with the issuer, and further proposes that the issuer would then have 30 calendar days to respond to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we propose under paragraph (c)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. We propose under paragraph (c)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

HHS proposes to add a new § 153.620(c)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the

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

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.620(c)(2) HHS proposes in paragraph (c)(5)(i) that HHS would notify the issuer of payments received that the issuer has not adequately substantiated, and in new proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. Therefore, the continued failure to comply with the audit requirements and provide the necessary information to substantiate the transfer amounts under review could result in HHS recouping up to 100 percent of the risk adjustment (including high-cost risk pool) payments, or increased risk adjustment (including high-cost risk pool) charges, made to an issuer for the applicable benefit year(s) that are the subject of the audit.

We note that any risk adjustment payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state

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market risk pool in the applicable benefit year.⁷⁵ We note that any high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis to other issuers in the relevant national market in the form of a reduced high-cost risk pool charge in the applicable benefit year. HHS would not, however, re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c).

We seek comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests.

5. EDGE Discrepancy Materiality Threshold

As stated in § 153.710(a) through (c), an issuer of a risk adjustment covered plan must provide to HHS, through their EDGE server,⁷⁶ access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS for a benefit year.

Consistent with § 153.730, to be considered for risk adjustment payments and charges, issuers of risk adjustment covered plans must submit their respective EDGE data by April 30 of the year following the applicable benefit year. At the end of the EDGE data submission process, HHS issues final EDGE server reports⁷⁷ which reflect an issuer's data that was successfully submitted

⁷⁵ See the 2016 Payment Notice final rule, 80 FR 10780 – 10781.

⁷⁶ This is also known as the dedicated distributed data collection environment.

⁷⁷ These reports are: Enrollee (Without) Claims Summary (ECS), Enrollee (Without) Claims Detail (ECD), Frequency Report by Data Element for Medical Accepted Files (FDEMAF), Frequency Report by Data Element for Pharmacy Accepted Files (FDEPAF), Frequency Report by Data Element for Supplemental Accepted Files (FDESAF), Frequency Report by Data Element for Enrollment Accepted Files (FDEEAF), Claim and Enrollee Frequency Report (CEFR), High Cost Risk Pool Summary (HCRPS), High Cost Risk Pool Detail Enrollee (HCRPDE), Risk Adjustment Claims Selection Summary (RACSS), Risk Adjustment Claims Selection Detail (RACSD), Risk Adjustment Transfer Elements Extract (RATEE), Risk Adjustment Risk Score Summary (RARSS), Risk Adjustment Risk Score Detail (RARSD), Risk Adjustment Data Validation Population Summary (RADVPS),

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

HHS reviews all reported EDGE discrepancies to evaluate the implications of each incorrect data submission for risk adjustment transfers and risk adjustment data validation. For risk adjustment transfers calculated under the state payment transfer formula, HHS evaluates whether the reported EDGE discrepancy is material and has a process to address incorrect EDGE data submissions that have a material impact on risk adjustment transfers for a state market risk pool.^{78,79} Currently, HHS uses the same materiality threshold for reconsideration requests set forth in § 156.1220(a)(2) for determining whether the EDGE discrepancy has a material impact on the risk adjustment transfers calculated under the state payment transfer formula.

Consequently, the reported EDGE discrepancy is considered material if the amount in dispute is equal to or exceeds the lower of either \$10,000 or one percent of the total estimated transfers in the applicable state market risk pool. After analyzing reported EDGE discrepancies in prior benefit years, we propose to codify a materiality threshold for EDGE discrepancies and also propose to establish a higher materiality threshold for EDGE discrepancies. More specifically, we propose the following materiality threshold for EDGE discrepancies: the amount in dispute

Risk Adjustment Payment Hierarchical Condition Category Enrollee (RAPHCCER), Risk Adjustment User Fee (RAUF).

⁷⁸ See, for example, <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2019-QQ-Guidance.pdf>. Also see 83 FR 16970 through 16971.

⁷⁹ HHS may also take action on reported material EDGE discrepancy if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

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must equal or exceed \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less.⁸⁰ Where an identified material EDGE discrepancy negatively affects the issuer without having a negative effect on other issuers within the state market risk pool, issuers would be required to adhere to the initial data submission and accept the consequences of the data submission, even when the monetary impact of the inaccuracy on the issuer submitting incorrect data is potentially substantial. Therefore, HHS would generally only take action on material discrepancies that harm other issuers in the same state market risk pool.⁸¹

We propose to amend § 153.710, by creating new paragraph (e) and redesignating paragraphs (e), (f) and (g), as (f), (g) and (h) respectively, to capture the proposed EDGE discrepancy materiality threshold and propose to apply it beginning with the 2020 benefit year.⁸² We believe this increased materiality threshold will reduce burden on issuers having to submit additional data to HHS when a discrepancy is determined to be potentially material and allow more certainty and stability for risk adjustment transfers. If a reported EDGE discrepancy is determined to not meet the materiality threshold, HHS would take no action on the discrepancy and the issuer's data submission would remain as submitted by the data submission deadline for the applicable benefit year.

While HHS generally only takes action on reported material EDGE discrepancies that are determined to harm other issuers, issuers must continue to report and describe any identified

⁸⁰ We are not proposing any changes to the materiality threshold for reconsideration requests in § 156.1220(a)(2).

⁸¹ Consistent with the current process, HHS may also take action on reported material EDGE discrepancies if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

⁸² The deadline for submission of 2020 benefit year risk adjustment data is April 30, 2021. See 45 CFR 153.730. As such, the EDGE discrepancy reporting process for the 2020 benefit year will not begin until May 2021.

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EDGE discrepancy to HHS in a format specified by HHS for each benefit year. Issuers must report all data discrepancies in order to permit HHS to determine whether such an error is material and actionable and to evaluate the impact on other issuers in the state market risk pool.

We seek comment on this proposal.

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

If a state is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. As noted previously in this proposed rule, for the 2022 benefit year, HHS will be operating the risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee.⁸³ 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-25 established federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(B) of Circular No. A-25 to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection. The risk adjustment program also contributes to consumer confidence in

⁸³ 78 FR 15416 through 15417.

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the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2021 Payment Notice, we calculated the federal administrative expenses of operating the risk adjustment program for the 2021 benefit year to result in a risk adjustment user fee rate of \$0.25 PMPM based on our estimated costs for risk adjustment operations and estimated billable member months for individuals enrolled in risk adjustment covered plans. For the 2022 benefit year, we 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 2022 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for the 2022 benefit year will be approximately \$60 million, and the risk adjustment user fee would be \$0.25 PMPM. The risk adjustment user fee costs for the 2022 benefit year are expected to remain steady from the prior 2021 benefit year estimates. However, we project a small decline in billable member months in the individual and small group markets overall in the 2022 benefit year based on the declines observed in the 2019 benefit year. We seek comment on the proposed risk adjustment user fee for the 2022 benefit year. We will continue to examine the costs and enrollment projections for the 2022 benefit year, particularly as we receive more

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information on the impact of the coronavirus disease 2019 (COVID-19) PHE, and propose to incorporate any such newly available data to update the final 2022 benefit year risk adjustment user fee rate that we would announce in the final rule. We seek comment on these estimates and the use of any newly available data to update the estimates to reflect any emerging cost or enrollment trends for the final 2022 benefit year user fee.

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

To ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS-RADV) under §§ 153.350 and 153.630 in any state where HHS is operating risk adjustment on a state's behalf. The purpose of HHS-RADV is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the HHS-operated risk adjustment program. HHS-RADV also ensures that risk adjustment transfers reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor data quality, thereby helping to ensure that the HHS-operated risk adjustment program assess charges to issuers with plans with lower-than-average actuarial risk while making payments to issuer with plans with higher-than-average actuarial risk. HHS-RADV consists of an initial validation audit and a second validation audit.⁸⁴ Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to the issuer's initial validation auditor for data validation. Each issuer's initial validation audit is followed by a second validation audit,

⁸⁴ 45 CFR 153.630(a) through (c).

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which is conducted by an entity HHS retains to verify the accuracy of the findings of the initial validation audit.

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

In 2020 Payment Notice, we codified several exemptions from the HHS-RADV requirements. In this rule, we propose to codify the previously established exemption⁸⁵ for issuers who only offer small-group carryover coverage in the state during the benefit year being audited at new proposed § 153.630(g)(4). As we discussed in the 2020 Payment Notice, under this policy, a small group market issuer with off-calendar year coverage who exits the market but has only carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold in the state) would be considered an exiting issuer and would be exempt from HHS-RADV for the benefit year with the carry-over coverage.⁸⁶

We also propose to codify the previously established exemption⁸⁷ for issuers who are the sole issuer in a state market risk pool during the benefit year that is being audited at new proposed § 153.630(g)(5). As we discussed in the 2020 Payment Notice, for single issuer market risk pool(s), there are no risk adjustment transfers calculated under the state payment transfer formula and thus, no payment or financial accountability to other issuers for that risk pool.⁸⁸ As such, a sole issuer in a state market risk pool is not required to participate in the HHS-operated risk adjustment program (except for purposes of high-cost risk pool payments and charges) for that state market risk pool. However, if the sole issuer was participating in multiple risk pools in the state during the year that is being audited, that issuer will be subject to HHS-RADV for those

⁸⁵ 84 FR 17503 through 17504.

⁸⁶ Ibid.

⁸⁷ 84 FR 17504.

⁸⁸ Ibid.

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risk pools with other issuers that had risk adjustment transfers calculated under the state payment transfer formula.

These exemptions do not introduce new policies; instead, the proposed amendments to § 153.630(g) are simply to codify these previously established exemptions in regulation. We also clarify that any issuer that qualifies for the small group carryover coverage exemption in new proposed paragraph (g)(4) would not have its risk score and its associated risk adjustment transfers adjusted due to its own risk score error rate, as the issuer would not have participated in HHS-RADV for the benefit year in which it only offered the small group carryover coverage. However, that issuer's risk score and resulting risk adjustment transfers could be subject to HHS-RADV adjustments if other issuers in that state market risk pool were outliers and received HHS-RADV risk score error rates for that benefit year.

We solicit comments on these proposals.

b. IVA Requirements (§ 153.630(b)(3))

In accordance with § 153.630(b)(3), an issuer must ensure that its IVA Entity is reasonably free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question. In prior rulemaking, we explained that to meet this standard, the IVA Entity, among other things, may not have had a role in establishing any relevant internal controls of the issuer related to the risk adjustment data validation process when HHS is operating risk adjustment on behalf of a state, or serve in any capacity as an advisor to the issuer regarding the IVA.⁸⁹ In this proposed rule, we propose to amend this standard and clarify that in order to demonstrate that the IVA Entity is reasonably free of conflicts, the IVA Entity must also not have or previously have had a role in establishing

⁸⁹ See 79 FR 13758.

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any relevant internal controls of the issuer related to risk adjustment or the EDGE server data submission process for the applicable benefit year for which the IVA Entity is performing the IVA on behalf of the issuer. Additionally, the IVA Entity must also not have served in any capacity as an advisor to the issuer regarding the risk adjustment or EDGE server data submission for the applicable benefit year. For example, the IVA Entity cannot serve as the issuer's third party administrator (TPA) for purposes of the EDGE data submission for HHS-operated risk adjustment in the 2020 benefit year and serve as the IVA Entity for that issuer for the 2020 benefit year. We are proposing these changes because HHS is concerned about conflicts of interest that could arise if the same entity assists or completes the EDGE data submissions for an issuer for an applicable benefit year, and then also serves as the IVA Entity auditing the submission of that data in HHS-RADV. This proposal is in addition to the requirements set forth in 2014 and 2015 Payment Notices.⁹⁰ We seek comment on this proposal.

c. HHS-RADV Administrative Appeals

In the 2015 Payment Notice, we established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain PPACA programs, including the calculation of risk adjustment charges, payments and user fees.⁹¹ In the 2018 Payment Notice final rule, we extended this three-level administrative appeal process to permit issuers to dispute the findings of a second validation audit with respect to the 2016 benefit year HHS-RADV and beyond.⁹² Issuers are not permitted to use the discrepancy reporting or administrative appeal

⁹⁰ The 2014 Payment Notice final rule required that that issuers ensure that IVA Entities are reasonably capable of performing the audit, the audit is completed, the auditor is free from conflicts of interest, and the auditor submits information regarding the IVA to HHS in the manner and timeframe specified by HHS. 78 FR 15410 at 15437. The 2015 Payment Notice final rule established standards and guidelines regarding the qualifications of the IVA Entity, including further details on the conflict of interest standards. 79 FR 13744 at 13758-13759.

⁹¹ 78 FR 13818 through 13820.

⁹² 81 FR 94106.

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processes under §§ 153.630(d)(2) and 156.1220, respectively, to contest the IVA findings, because HHS does not conduct the IVA or produce those results.⁹³ Instead, issuers should review their IVA findings and discuss any concerns with its IVA Entity prior to attesting to and submitting those results to HHS.⁹⁴ The existing regulation at § 153.630(d)(2) captures this policy. In this rule, we propose conforming amendments to paragraph (d)(3) to similarly add “if applicable” to the reference to an issuer’s ability to appeal the findings of the second validation audit to ensure these regulatory provisions also appropriately capture this limitation.⁹⁵ As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and second validation audit will receive a Second Validation Audit Findings Report and therefore have the right to appeal the second validation audit findings.⁹⁶ We seek comment on these proposed amendments.

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

In the 2020 Payment Notice,⁹⁷ we finalized an updated timeline for the publication, collection, and distribution of HHS-RADV adjustments to transfers. This timeline allowed issuers to report HHS-RADV adjustments in a later MLR reporting year and to consider, in accordance with any guidance from the state DOIs, these adjustments in rate setting during a later benefit year (specifically, the year in which the HHS-RADV adjustments are collected and paid). Beginning with 2019 benefit year HHS-RADV, we propose to revert to the previous

⁹³ Ibid.

⁹⁴ See, for example, Sections 9.1, 9.5 and 9.7 of the “2017 Benefit Year Protocols PPACA HHS Risk Adjustment Data Validation, Version 2.0,” August 10, 2018.

⁹⁵ As detailed further below, we propose similar conforming amendments to the references to an issuer’s ability to appeal the findings of the second validation audit in 45 CFR 156.1220(a)(1) and (a)(3).

⁹⁶ 84 FR 17495.

⁹⁷ 84 FR 17506 through 17507.

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schedule⁹⁸ for the collection of HHS-RADV charges and disbursement of payments in the calendar year in which HHS-RADV results are released (for example, collection and disbursement of 2021 benefit year HHS-RADV adjustments would begin in summer or fall of 2023).

HHS publishes the final summary report of risk adjustment transfers (without HHS-RADV adjustments) and information on risk adjustment default charges for the applicable benefit year in the summer of the year after the applicable benefit year (typically June 30th of the year after the applicable benefit year), and issuers report those risk adjustment amounts in their MLR reports by July 31st of the year after the applicable benefit year.⁹⁹ Payment and collection of these risk adjustment transfer and default charge amounts generally occurs in August and September of the year after the applicable benefit year. HHS separately reports the HHS-RADV adjustments and information on default data validation charges for the applicable benefit year approximately one year after the final summary report of risk adjustment transfers for that benefit year is published (typically 2 years after the applicable benefit year in August¹⁰⁰).

Under the current HHS-RADV timeline, HHS begins collection and disbursement of HHS-RADV adjustments and default data validation charges and allocations 2 years after announcing the HHS-RADV adjustments (for example, collection and disbursement of 2017

⁹⁸ See 79 FR 13768 and 13769. Also see, for example, Table 3 in the document entitled “Proposed Key Dates for Calendar Year 2019: Qualified Health Plan (QHP) Certification in the Federally-facilitated Exchanges (FFE)s; Rate Review; and Risk Adjustment.” Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Key-Dates-Table-for-CY2019.pdf>.

⁹⁹ The one exception is for the rare circumstances that HHS is unable to collect full risk adjustment charges in a state market risk pool or high-cost risk pool charges in a national market risk pool. In such situations, issuers receiving lesser payments can reflect the reductions in their MLR reports.

¹⁰⁰ HHS-RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID-19-related delay in HHS-RADV activities for the 2019 benefit year. See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

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benefit year HHS-RADV adjustments will begin in 2021¹⁰¹). For MLR reporting purposes, under the current approach finalized in the 2020 Payment Notice, issuers will reflect the HHS-RADV adjustment amounts and default data validation charges and allocations in the MLR reporting year in which collections and payments of those amounts occur. Subject to approval by state DOIs, issuers are also permitted to reflect these amounts in rate setting for the same benefit year in which those amounts are paid or collected. For example, 2017 benefit year HHS-RADV adjustments and default data validation charges and allocations were announced in August 2019 and issuers will report these amounts in the 2021 MLR reporting year (MLR reports filed in 2022), the same year that the adjustments and default data validation charges will be collected and paid. Additionally, subject to permission by state DOIs, issuers were permitted to account for the impacts of those 2017 benefit year HHS-RADV adjustments in rate setting for the 2021 benefit year.

The current timeline was intended to address stakeholder concerns regarding the predictability of HHS-RADV adjustments, especially for the initial payment year. However, since the publication of the 2020 Payment Notice, we have received feedback stating that the extended timeline has not provided the increased flexibility intended by the policy and instead has introduced undue complexity. Specifically, stakeholders have expressed concern that this policy conflicts with state requirements for financial accounting, and can negatively impact their MLR rebate position, particularly if the issuer experiences substantial changes in enrollment over the 3-year MLR calculation period.¹⁰²

¹⁰¹ <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf>.

¹⁰² Issuer MLRs are calculated using a three-year average. See section 2718(b)(1)(B)(ii) of the PHS Act and 45 CFR 158.220(b).

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Although the operational timelines of the risk adjustment program and the nature of HHS-RADV causes HHS-RADV results to always be at least a year behind the associated risk adjustment transfers report, we have continued to consider these issues. We adopted the current timeline to provide issuers (and states) with more options on how and when to account for the financial impacts from HHS-RADV. However, as noted above, stakeholder feedback has indicated that the approach did not achieve its policy goal and instead introduced unnecessary complexity. In this rule, we therefore propose to revert to the previous schedule for collection and disbursement of HHS-RADV adjustments and default data validation charges and begin such activities in the summer or fall of the calendar year in which HHS-RADV results are released. For example, collection of 2021 benefit year HHS-RADV adjustments and default data validation charges and disbursement of such amounts would begin in summer or fall of 2023. In support of the new proposed timeline for collection and disbursement of HHS-RADV adjustments and default data validation charges, HHS would need to release the applicable benefit year's report on HHS-RADV adjustments and default data validation charges earlier in the year so the amounts are available for issuers to use for MLR reporting purposes. We therefore also propose to release the applicable benefit year's HHS-RADV summary report no later than early summer, and require issuers to report those amounts in the MLR reports submitted by July 31st of the same calendar year in which the results are released. For example, as proposed, the summary report on 2021 benefit year HHS-RADV adjustments and default data validation charges and allocations would be released no later than early summer 2023, and issuers would be instructed to report these amounts in the 2022 MLR reporting year (MLR reports that include 2022 benefit year data that are submitted by July 31, 2023). We would then collect and disburse HHS-RADV adjustments and default data validation charges and allocations

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in summer or fall of the calendar year in which HHS-RADV results are released (for example, collection and disbursement of 2021 benefit year HHS-RADV adjustments and default data validation charges would begin in summer or fall of 2023). We note the Unified Rate Review Template (URRT) instructions currently permit issuers and states to consider HHS-RADV impacts in rates for the year when these amounts will be collected and disbursed, however if this proposal is finalized, we would remove this flexibility from the URRT instructions.

The new proposed timeline would help mitigate concerns regarding the incongruity with state financial accounting requirements, as well as potential undue impacts of HHS-RADV adjustments on MLR rebate liability, which could result from the HHS-RADV adjustments being reported outside the 3-year MLR aggregation window and thus potentially distorting the MLR experience of the benefit year to which HHS-RADV adjustments apply. This change may also help mitigate the impact of any substantial changes in enrollment between benefit years.

We propose to begin this policy with the collection and disbursement of HHS-RADV adjustments and default data validation charges for the 2019 benefit year. However, due to the delay in the 2019 benefit year HHS-RADV,¹⁰³ the timing of collections and disbursements is different for the 2019 benefit year. If finalized as proposed, HHS would publish the 2019 benefit year HHS-RADV Summary Report in early summer of 2022. HHS will also publish the 2020 benefit year HHS-RADV Summary report in early summer of 2022.¹⁰⁴ Issuers would be required

¹⁰³ HHS-RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID-19-related delay in HHS-RADV activities for the 2019 benefit year. See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

¹⁰⁴ In the proposed 2020 HHS-RADV Amendments Rule (85 FR 33595), we proposed a transition from the prospective application of HHS-RADV adjustments to a concurrent application beginning with 2020 benefit year HHS-RADV. In that proposed rule, we also solicited comment on an alternative timeline for the transition beginning with 2019 benefit year HHS-RADV. We believe that either of these timelines to transition to a concurrent application of HHS-RADV results is compatible with the proposal in this rule to change the timing of HHS-RADV collections and disbursements.

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to include any payments and charges reflected on these reports, along with risk adjustment transfers for the 2021 benefit year, in their 2021 MLR reports, which must be filed by July 31, 2022. Finally, HHS would begin collecting both 2019¹⁰⁵ and 2020 HHS-RADV adjustments to transfers for non-exiting issuers along with any default data validation charges imposed for these two benefit years and disbursing related payments in late summer or early fall of 2022. Issuers would be required to report the 2019 and 2020 benefit year HHS-RADV adjustments to transfers in their MLR reports for the 2021 MLR reporting year (MLR reports that include 2021 benefit year data that are submitted by July 31, 2022). We seek comment on this proposal and whether any consideration should be made in the transition to this policy to account for 2017 and 2018 benefit year HHS-RADV collection and disbursement of payments and charges (under the current timeline) also occurring in 2021 and 2022.

e. Second Validation Audit and Error Rate Discrepancy Reporting Windows

Under § 153.630(d)(2), issuers have 30 calendar days to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy report, in the manner set forth by HHS, to dispute the foregoing. As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and SVA receive SVA findings.¹⁰⁶ We propose to amend paragraph (d)(2) to shorten the window to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy, to within 15 calendar days of the notification by HHS, beginning with the 2020 benefit year HHS-RADV. The proposed shorter discrepancy reporting timeframes are intended to ensure that we can resolve as many issues as possible in advance of publication of the

¹⁰⁵ See <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

¹⁰⁶ 84 FR 17495.

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

We seek comment on the proposed shortened discrepancy windows under proposed § 153.630(d)(2).

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

As detailed earlier in this preamble, on September 2, 2020, HHS issued an interim final rule on COVID-19 wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year to align with the relaxed enforcement policy announced in guidance.¹⁰⁷ For the 2021 benefit year and beyond, we propose to permanently adopt these risk adjustment reporting requirements for all health insurance issuers in the individual and small group markets who elect to offer premium credits during a PHE

¹⁰⁷ See, for example, “Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency,” August 4, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

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declared by the Secretary of HHS (declared PHE)¹⁰⁸ if the premium credits are permitted by HHS in future benefit years. Specifically, we propose that issuers of risk adjustment covered plans that provide temporary premium credits when permitted by HHS in future benefit years must report to their EDGE servers adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums. Elsewhere in this proposed rule, we also propose to clarify that HHS's calculation of risk adjustment payment and charges for the 2021 benefit year and beyond under the state payment transfer formula would be calculated using the statewide average premium that reflects actual premiums billed, taking into account any temporary premium credits provided as a reduction in premium for the applicable months of coverage when permitted by HHS in future benefit years.

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

¹⁰⁸ The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: a) a disease or disorder presents a public health emergency; or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

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

Therefore, we believe that requiring issuers that offer temporary premium credits, when permitted by HHS, to accurately report to the EDGE server the adjusted, lower premium amounts actually charged to enrollees is most consistent with existing risk adjustment program requirements and mitigates the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts charged to enrollees, while not imposing additional financial burdens on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts. We request comment on this proposal.

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

1. Definitions (§ 155.20)

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

We propose to amend § 155.20 to add a definition of QHP issuer direct enrollment technology provider, which we propose to mean a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230. We also propose that this definition of QHP issuer direct enrollment technology provider explicitly acknowledge that a web-broker may also provide services to QHP issuers as a QHP issuer direct enrollment technology provider to clarify that being a web-broker does not preclude that entity from providing technology services or an information technology platform to QHP issuers to facilitate QHP issuers' participation in direct enrollment. In addition, we propose to modify the current

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definition of direct enrollment technology provider in § 155.20 to distinguish it from the new proposed definition of QHP issuer direct enrollment technology provider by renaming the term agent or broker direct enrollment technology provider. We propose these new and modified definitions to capture the full array of potential arrangements between technology companies and entities seeking to use the direct enrollment pathways to facilitate enrollments in QHPs offered in an FFE or SBE-FP in a manner that constitutes enrollment in the Exchange. To align with these proposed new and modified definitions, we further propose to modify the definition of web-broker to replace the current last sentence, which states that the term includes a direct enrollment technology provider, to instead indicate a web-broker includes an agent or broker direct enrollment technology provider.

In the 2020 Payment Notice, we amended § 155.20 to define “direct enrollment technology provider” to mean “a type of web-broker business entity that is not a licensed agent, broker, or producer under [s]tate law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221.”¹⁰⁹ This definition captures instances in which an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, engages the services of or creates a technology company that is not licensed as an agent, broker, or producer to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. When the technology company is not itself licensed as an insurance agency or brokerage, the current framework establishes that

¹⁰⁹ See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters; Final rule, 84 FR 17454 at 17562 (April 25, 2019).

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these technology companies are a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless indicated otherwise.¹¹⁰

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

¹¹⁰ For example, § 155.220(d)(2) exempts direct enrollment technology providers from the training requirement that is part of the annual FFE registration process for agents and brokers.

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

We seek comment on this proposal.

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b. Definition of Exchanges

Since 2013, qualified individuals and qualified employers have been able to purchase QHPs—private health insurance that has been certified as meeting certain standards—through competitive marketplaces called Exchanges or Health Insurance Marketplaces. 45 CFR 155.20 defines an Exchange as a governmental agency or non-profit entity that meets the applicable standards of part 155 and makes QHPs available to qualified individuals and/or qualified employers. In this proposed rule, the word “Exchanges” collectively refers to, but is not limited to, the following models of Exchange: State Exchanges, also called State-based Exchanges (SBEs); Federally-facilitated Exchanges (FFE); State-based Exchanges on the Federal platform (SBE-FPs); and the new proposed Direct Enrollment (DE) Exchanges (FFE-DEs, SBE-FP-DEs, or SBE-DEs). When we refer to “the Exchange(s)” and “an Exchange,” we are referring to Exchanges established and operated by a state (including a regional Exchange or subsidiary exchange) or by HHS.

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

To continue our efforts to standardize regulatory references to web-brokers, we propose to replace all references in § 155.205(c) to “an agent or broker subject to § 155.220(c)(3)(i)” with the term “web-broker.” In the 2020 Payment Notice, we amended § 155.20 to define the term “web-broker”¹¹¹ to mean an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, that is registered with an Exchange under § 155.220(d)(1) and develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with the selection of and enrollment in QHPs offered through the Exchange (a process referred to as direct enrollment). We also amended §§ 155.220 and 155.221 to incorporate the term web-broker

¹¹¹ See 84 FR 17563.

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

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

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

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added to their websites as a condition of participation in the FFE EDE program. We note this proposed flexibility would not absolve QHP issuers and web-brokers from complying with website content translation requirements under paragraphs (c)(2)(iv)(B) and (C) that is unrelated to their participation in the FFE EDE program within the applicable timeframes.¹¹² For example, a QHP issuer's or web-broker's implementation of the Exchange eligibility application on its website for purposes of participation in the FFE EDE program would be considered content added to its website to participate in the FFE EDE program and would be afforded the additional time for translation into applicable languages. However, QHP issuer website content that was not added to participate in the FFE EDE program and that is subject to the paragraph (c)(2)(iv)(C) requirements, such as Summaries of Benefits and Coverage or provider directories, would not be afforded additional time for translation into applicable languages. Similarly, website content related to a web-broker's participation in Classic DE that is subject to the paragraph (c)(2)(iv)(C) requirements, such as plan selection pages displaying QHPs, would not be afforded additional time for translation into applicable languages beyond the one year after the web-broker has been registered with the Exchange.

This proposed change does not alter the additional accessibility requirements QHP issuers and web-brokers must comply with under paragraphs (c)(2)(i), (ii), and (iii). This includes oral interpretation services, including telephonic interpreter services in at least 150 languages, written translations, and applicable tagline requirements for website content and documents critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or

¹¹² See also "Guidance and Population Data for Exchange, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and § 156.250," March 30, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf>.

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enrollees. These obligations on QHP issuers and web-brokers would continue to protect individuals with LEP and assure that these entities are taking the necessary steps to provide meaningful access to LEP individuals, as required under title VI and the non-discrimination provisions contained in section 1557 of the PPACA.

In addition, this proposed revision also would not extend to QHP issuers and web-brokers approved to participate in a state that elects to use a direct enrollment option as proposed in § 155.221(j) of this rule. Under this proposed rule, QHP issuers and web-brokers that participate in a state that elects to implement the direct enrollment option as proposed in paragraph (j) of this rule would not be afforded the flexibility to delay website translations as otherwise permitted under § 155.205(c)(2)(iv)(C), with or without the proposed revisions in this rule. Thus, website content that is intended for consumers, qualified individuals, applicants, or enrollees on an enrollment website maintained by a web-broker or QHP issuer within a relevant state pursuant to new proposed § 155.221(j) must be translated into any non-English language that is spoken by a LEP population that makes up 10 percent or more of the total population of the relevant state, as soon as the web-broker or QHP issuer begins operating in that state.

We believe that providing QHP issuers and web-brokers participating in the FFE EDE program with additional time to come into compliance with the website content translation requirement for the website content added to their websites to participate in the FFE EDE program is warranted given the significant resources associated with entering a new state market and obtaining approval to participate in the FFE EDE program generally as well as the significant cost of third-party EDE audit requirements. Given these considerations, we believe that this proposed revision will provide an incentive for such entities to enter markets where there is a significant number of LEP individuals, while also ensuring that website content is

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accessible for individuals with LEP within a reasonable period of time. We are of the view that this flexibility will enable interested QHP issuers and web-brokers participating in the FFE EDE program to test markets before incurring significant additional translation costs. We are also of the view that this proposal would enable smaller QHP issuers and web-brokers to compete more effectively in state markets. In addition, lessening the burden on QHP issuers and web-brokers participating in the FFE EDE program should encourage entities that are interested in entering markets with large numbers of LEP individuals to focus on enhancing and tailoring services to meet the needs of consumers, qualified individuals, applicants, qualified employers, qualified employees, or enrollees. We believe this proposed change that would provide additional time for such entities to come into compliance with website content translation requirements will allow them more flexibility and time to assess the viability of a market prior to committing substantial resources to completing translations of website content added to their websites as a condition of participation in the FFE EDE program. The proposal could thereby ease entry of QHP issuers and web-brokers into relevant states, and allow costs associated with translation services and the related third-party audit to be spread out over time.

We seek comment on whether this added flexibility for QHP issuers and web-brokers participating in the FFE EDE program in relevant states could impact accessibility to Exchange coverage for LEP communities, or otherwise negatively impact the operation of and consumer access to Exchanges. In addition, we seek comment from QHP issuers and web-brokers as to whether this proposed change would foster investment in states where there is a significant LEP community and provide additional incentives for such entities to expand into relevant states. We would particularly like to hear from smaller QHP issuers and web-brokers as to whether the proposed flexibility provides sufficient time to encourage entry into states that meet the 10

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percent LEP population threshold. Lastly, we seek comment from assisters about any impacts this proposed change would have on their ability to work with web-brokers and use EDE websites as proposed in § 155.220(c)(3)(iii) in this proposed rule when assisting members of the LEP community with Exchange enrollment.

3. Navigator Program Standards (§ 155.210)

Sections 1311(d)(4)(K) and 1311(i) of the PPACA require the Secretary to establish a Navigator program under which HHS awards grants to entities to conduct public education activities to raise awareness of the availability of QHPs, distribute fair and impartial information concerning enrollment in QHPs and the availability of APTC and CSRs, and facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary, in collaboration with states, to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. We have implemented the statutorily required Navigator duties through regulations at §§ 155.210 (for all Exchanges) and 155.215 (for Navigators in FFEs). Certified Application Counselors (CACs) duties have been implemented through regulations at § 155.225.

We propose allowing, but not requiring, Navigators and CACs in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent

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permitted by state law. For a discussion of the proposal to allow Navigators and CACs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment, please see the preamble to § 155.220.

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

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

In the 2020 Payment Notice, we proposed, but did not finalize, a modification of our policy that prohibits Navigators and CACs (together referred to here as “assisters”) from using web-broker websites to assist with QHP selection and enrollment.¹¹³ At the time, adoption of EDE functionality by web-brokers was still limited, and we decided to focus on the implementation and oversight of the EDE pathway before revisiting the current policy regarding assister use of web-broker websites. Since then, EDE functionality has become more user-friendly and increasingly more consumers are using the EDE pathway to enroll in Exchange coverage. Some stakeholders have continued to express interest in allowing for the use of web-broker non-Exchange websites by assisters to broaden the range of consumers these websites serve, to improve the consumer shopping and enrollment experience, and to leverage assisters’ expertise in navigating more complex enrollment cases. For these reasons, we are revisiting these issues and propose to modify the current policy that prohibits assisters from using web-broker websites to assist with QHP selection and enrollment.

Our proposal would permit, but not require, assisters in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided the non-Exchange website meets certain conditions. The conditions we propose to require for

¹¹³ See 84 FR 17515 through 17521.

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these types of arrangements are designed to ensure that assisters are able to use web-broker non-Exchange websites while still meeting their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers, and that each web-broker's website captures and transmits assister data to the Exchange to facilitate HHS oversight of the entities using the EDE pathway. To promote state flexibility and autonomy, we propose to provide states with a State Exchange that does not rely on HealthCare.gov the discretion to permit their assisters to use web-broker non-Exchange websites. Alternatively, states with a State Exchange may instead choose to preserve the prohibition on assister use of web-broker websites.

Direct enrollment is a mechanism for approved third parties to assist consumers with QHP plan selection and enrollment through a non-Exchange website in a manner considered to be through the Exchange. Web-brokers are one of the entities eligible to become a direct enrollment entity. There are currently two direct enrollment pathways available in states with FFEs and SBE-FPs – Classic Direct Enrollment (Classic DE) and EDE. Classic DE is the original version of direct enrollment, which utilizes a 'double redirect' from a direct enrollment entity's non-Exchange website to HealthCare.gov where the eligibility application is submitted and an eligibility determination is made by the Exchange, and then back to the direct enrollment entity's non-Exchange website for QHP shopping and plan selection consistent with applicable requirements in §§ 155.220(c)(3)(i), 155.221, 156.265 and/or 156.1230(b). EDE is the version of direct enrollment which allows consumers to complete all steps in the application, eligibility and enrollment processes on the direct enrollment entity's non-Exchange website consistent with applicable requirements in § 155.220(c)(3)(ii), 155.221, 156.265 and/or 156.1230(b). EDE uses application programming interfaces (APIs) that are made available, owned, and maintained by

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CMS to transfer data between HealthCare.gov and the direct enrollment entity's non-Exchange website.

Web-brokers have developed innovative tools to support consumers shopping for QHP coverage through their non-Exchange websites for both Classic DE and EDE that assisters and the consumers they assist may find helpful when shopping for and enrolling in QHPs offered through Exchanges. In addition, some web-brokers have expressed interest in leveraging assisters' expertise in navigating more complex enrollment cases to provide additional support to the consumers they serve. At the same time, assisters have expressed a desire to obtain access to an improved consumer experience by leveraging innovative and unique consumer assistance tools and display features many web-brokers have developed for Classic DE and EDE. Additionally, some assisters have expressed a desire to have access to real-time information on the status of submitted applications and enrollments that is available through current EDE platform web portals to more effectively assist consumers. Although we are not proposing to require web-brokers to develop such web portals, we recognize that some web-brokers may consider developing web portals to enable assisters, with the consent of the consumer, to gain easy access to real-time information for each of the consumers they assist using a web-broker's non-Exchange website. Where a web-broker's non-Exchange website meets applicable requirements, we want to encourage this type of innovation to improve the experience for assisters and the consumers they assist with shopping for and enrolling in QHPs offered through an Exchange.

The implementation of EDE by a growing number of web-brokers has presented consumers with an additional method of applying for insurance affordability programs and selecting and enrolling in QHPs offered through Exchanges. We believe this additional

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enrollment pathway option should also be available to all FFE and SBE-FP assisters who provide application and enrollment assistance, when permitted under state law, provided there are safeguards in place to ensure that the information and help the assisters provide remains fair, accurate, and impartial. While we anticipate assisters and web-brokers would be most interested in exploring this flexibility for EDE, we believe assisters should also have the option to use the innovative and unique consumer-assistance tools and display features many web-brokers have developed to facilitate selection of QHPs offered through FFEs and SBE-FPs through Classic DE. We therefore clarify that this proposal, if finalized, would permit assisters in FFE and SBE-FP states to use a web-broker's non-Exchange website for Classic DE and EDE if applicable requirements are met and such arrangements are otherwise permitted under state law. As noted above, under this proposal, states with State Exchanges that do not use HealthCare.gov would also retain discretion to adopt a similar approach for assisters to permit the use of non-Exchange websites, or these states could maintain the current prohibition on the use of such websites by assisters.

We also anticipate that allowing FFE and SBE-FP assisters to use web-broker non-Exchange websites to enroll consumers in QHPs will encourage collaboration between assisters and web-brokers that will benefit consumers by providing them with the most appropriate support at each stage of the Exchange application, QHP selection, and QHP enrollment processes. We believe that it is essential for assisters to evolve by collaborating with new partners to better accomplish the shared goals of educating consumers and helping them to enroll in QHPs offered through Exchanges that best fit their needs. We further believe this proposal will empower assisters to use tools that may be available outside of the HealthCare.gov platform that can best help assisters to serve their consumers and expand their reach and impact.

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While we believe consumers working with assisters should have access to additional options for selection of and enrollment in QHPs offered through Exchanges that may be available through web-broker non-Exchange websites, we believe it is necessary to put safeguards in place to ensure assisters working with consumers using these sites continue to comply with the statutory and regulatory standards governing their role and duties. Sections 1311(i)(3)(B) and (i)(5) of the PPACA and their implementing regulation at § 155.210(e)(2) require Navigators to provide fair, accurate, and impartial information to consumers in connection with their role. A similar requirement applies to CACs under § 155.225(c)(1). Under § 155.210(d), Navigators are also prohibited from being a health insurance issuer or issuer of stop loss insurance; a subsidiary of a health insurance issuer or issuer of stop loss insurance; or an association that includes members of, or lobbies on behalf of, the insurance industry; or receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any qualified individuals or employees in a QHP or a non-QHP. Finally, under §§ 155.210(b)(1) and (c)(1)(iv) (for all Navigators) and 155.215(a) (for Navigators in FFEs), Navigators must be free from any prohibited conflicts of interest. Similarly, CACs are prohibited under § 155.225(g)(2) from receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals in a QHP or non-QHP, and are required under § 155.225(d)(2) to disclose any relationships they or their sponsoring agencies have with QHPs or insurance affordability programs, or other potential conflicts of interest. These rules help ensure that assisters remain free from any influence that might interfere with their duty to provide consumers with the fair, accurate, and impartial information they need to make informed plan choices, while not influencing a consumer's ultimate QHP selection.

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We previously interpreted the requirement to provide fair, accurate, and impartial information to mean that assisters are prohibited from using a web-broker's non-Exchange website to provide QHP shopping, application, and enrollment assistance, unless the assister is using it as a reference tool to supplement the information available on HealthCare.gov.¹¹⁴ This approach was adopted due to concerns that web-brokers are not required to provide fair, accurate, and impartial information, and are not prohibited from recommending specific products, including QHPs, to their clients. Therefore, we concluded that assisters would be unable to use a web-broker website consistent with their duty to provide fair, accurate, and impartial information. Since then, we have expanded the requirements applicable to agents and brokers (including web-brokers) facilitating enrollment of qualified individuals, qualified employers, or qualified employees in QHPs offered through the FFEs and SBE-FPs, including web-brokers that host non-Exchange websites. This includes FFE standards of conduct that apply to agents, brokers, and web-brokers participating in Classic DE and EDE, as well as those who use the HealthCare.gov website when assisting Exchange consumers. For example, agents and brokers (including web-brokers) must provide consumers with correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the FFEs or SBE-FPs, and insurance affordability programs.¹¹⁵ In addition, agents and brokers (including web-brokers) must refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting HealthCare.gov), coercive, or discriminatory.¹¹⁶ Finally, the web-broker's non-Exchange website must provide consumers with the ability to view all QHPs offered through the Exchange,

¹¹⁴ See 79 FR 30239.

¹¹⁵ 45 CFR 155.220(j)(2)(i) and (l).

¹¹⁶ Id.

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not provide financial incentives such as rebates or giveaways, and not display QHP recommendations based on compensation the web-broker receives from QHP issuers.¹¹⁷ We believe that the combination of these requirements can be relied upon to ensure that assisters are continuing to meet their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers when assisting them with selection and enrollment in QHPs offered through the FFEs when using a web-broker's non-Exchange website.

We are proposing several amendments to § 155.220 to capture the flexibility for assisters in FFE and SBE-FP states to use web-broker non-Exchange websites to assist consumers. As noted previously in this proposed rule, this proposed flexibility would extend to both Classic DE and EDE options that web-brokers may offer to assist consumers in FFE and SBE-FP states. First, we propose at paragraph (c)(3)(iii)(A) for web-broker websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), for such websites to be eligible for use by assisters when otherwise permitted under state law. We note that web-brokers may obtain all QHP information they would be required to display in FFEs and SBE-FPs for assisters to be permitted to use their websites by integrating with the FFEs' Marketplace API.

For web-brokers operating in FFE and SBE-FP states, we propose an optional annual certification process at new proposed paragraph (c)(3)(iii)(B) under which a web-broker could be certified by the Exchange by attesting to its compliance with the requirements proposed in § 155.220(c)(3)(iii)(A). We propose that the optional annual certification process would be

¹¹⁷ See 45 CFR 155.220(c)(3)(i)(B), (C), and (L) (extending these requirements to Classic DE) and 155.220(c)(3)(ii)(A) (extending these requirements to EDE).

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integrated into the existing annual web-broker registration process, or could occur during another time of year. We propose to maintain a public list of approved web-brokers in FFEs or SBE-FPs and may add to that list information about whether a web-broker is certified, so that assisters may more easily identify web-broker websites they may seek to use in FFE and SBE-FP states, when such arrangements are permitted under state law.

The proposed amendments to § 155.220(c)(3)(iii)(A) also provide that if a web-broker non-Exchange website does not facilitate enrollment in all available QHPs in the state, it would be required to identify for consumers the QHPs, if any, for which the web-broker website does not facilitate enrollment by prominently displaying a standardized disclaimer provided by the Exchange, and in a form and manner specified by the Exchange. The disclaimer would state that the consumer can enroll in such QHPs through the Exchange-operated website, and would display a link to the Exchange website. We anticipate issuing further guidance on the form and manner in which the disclaimer should be displayed to ensure that it is clearly associated with any QHPs for which the web-broker does not facilitate enrollment. We are considering whether the disclaimer or a link to the disclaimer should replace the link or other mechanism the web-broker would otherwise display to allow a consumer to proceed with selecting and enrolling in a QHP, or whether the disclaimer should be displayed in some other fashion. We invite comments on what requirements should be adopted in reference to how this disclaimer should be displayed on a web-broker's non-Exchange website.

We note assisters, as part of providing information that is fair, accurate, and impartial, are prohibited from steering consumers to choose particular plans or recommend enrollment in any plan. With this general framework in mind, we encourage web-brokers who elect to make their non-Exchange websites available to assisters to consider developing innovative consumer

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assistance tools that could be used by assisters and the consumers they serve, including those related to displaying QHPs that are based on consumer preferences or based on algorithms that take into account unique consumer characteristics (for example, consumer's age, zip code, or family composition), but that are not based on compensation that the web-broker may receive from QHP issuers. Consistent with the existing prohibition in § 155.220(c)(3)(i)(L), if a web-broker makes its non-Exchange website available to assisters, the website may not display QHP recommendations based on compensation the web-broker receives from QHP issuers.¹¹⁸ Under our proposal, all of the other requirements outlined in §§ 155.220 and 155.221 that otherwise apply to web-broker non-Exchange websites would continue to apply to such websites when used by assisters. For example, a web-broker non-Exchange website made available to assisters would be required to refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting HealthCare.gov), coercive, or discriminatory. In addition, the web-broker non-Exchange website would have to provide correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the FFEs or SBE-FPs, and insurance affordability programs. We note that the proposed addition of § 155.220(n)(1) described in the preamble below that proposes to create flexibility for web-broker non-Exchange websites to display limited QHP details in certain circumstances and subject to certain requirements would not extend to web-broker non-Exchange websites used by assisters, which is why proposed § 155.220(c)(3)(iii)(A) begins with “[n]otwithstanding paragraph (n)(1) of this section.”

We still believe that, for assisters to be permitted to use a web-broker's non-Exchange website, there would need to be a mechanism to capture information about assisters assisting

¹¹⁸ See 45 CFR 155.220(c)(3)(i)(L).

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consumers with Exchange applications or QHP enrollment on the non-Exchange website and that would transmit that data to the Exchange. For example, the web-broker would need to capture and transmit assister unique ID numbers to HealthCare.gov. This information is necessary to facilitate HHS oversight of the direct enrollment program and these details are collected for agents and brokers that use web-broker non-Exchange websites. In FFEs and SBE-FPs, web-brokers that offer their non-Exchange websites for use with Classic DE include the redirect to HealthCare.gov for consumers to complete the eligibility application, and the eligibility application on HealthCare.gov includes fields to capture this information and would therefore comply with such a requirement. For web-brokers participating in FFEs and SBE-FPs that offer their non-Exchange website for use with EDE, as indicated in operational guidance, specifically the EDE User Interface Question Companion Guide, the eligibility application hosted on the web-broker non-Exchange website must contain the same fields to capture information that are included in the application on HealthCare.gov. We do not believe a regulatory change is needed to capture this requirement, but clarify that we would interpret the existing requirements for an eligibility application hosted on the web-broker's non-Exchange website to capture the information included on the HealthCare.gov application to mandate that web-brokers that offer their non-Exchange website for use by assisters must have a mechanism to capture identifying information about assisters assisting consumers with Exchange applications or QHP enrollment and must transmit such information to the Exchange.

Nothing we are proposing is intended to change the prohibition at § 155.210(d)(4) on Navigators receiving any consideration, in cash, or in kind, directly or indirectly, from any health insurance issuer or issuer of stop loss insurance in connection with enrollment of any qualified individuals or qualified employees in a QHP or non-QHP, or on the parallel prohibition on CACs

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receiving any consideration directly or indirectly from any health insurance issuer or issuers of stop-loss insurance at § 155.225(g)(2). Therefore, if the proposed changes outlined above are implemented, all assisters using web-broker non-Exchange websites in FFE and SBE-FP states would continue to be prohibited from receiving compensation related to the enrollment assistance they provide.

We seek comment on all of these proposals.

b. QHP Information Display on Web-broker Websites

We propose to provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for QHPs in certain circumstances. Currently, § 155.220(c)(3)(i)(A) requires that a web-broker non-Exchange website must disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c). To the extent that not all information required under § 155.205(b)(1) is displayed for a QHP, a web-broker must prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a link to the Exchange website. Section 155.220(c)(i)(D) similarly currently requires web-brokers to display all QHP data provided by an Exchange on its non-Exchange website used to participate in the FFE direct enrollment program (whether Classic DE or EDE). These display requirements have evolved over time as the Exchanges have matured. For example, in the early years of Exchange operations, we released a data file with limited QHP details (the QHP limited file) that provided web-brokers with a basic set of QHP data that could be used to satisfy the display requirement. In adopting this approach, we recognized that the Exchange may not have been able to provide web-brokers with certain data elements necessary to meet the § 155.205(b)(1) requirements, such

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as premium information, due to confidentiality requirements, web-broker appointments with QHP issuers, and state law. We also recognized some of the data elements, such as quality rating information, were not going to be available in the initial years of the Exchanges' operation.¹¹⁹ Display of these data elements from the QHP limited file data, in combination with a standardized disclaimer (the plan detail disclaimer), became the *de facto* minimum required to satisfy the web-broker's obligation to display QHP information on its non-Exchange website.

In new proposed § 155.220(n), we propose to establish an exception to the web-broker display requirements captured at paragraphs (c)(3)(i)(A) and (D). We propose to revise paragraph (c)(3)(i)(A) to require a web-broker non-Exchange website to disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), except as permitted under § 155.220(n). We propose a similar revision to § 155.220(c)(3)(i)(D). At new proposed paragraph (n), we propose certain flexibilities regarding display of QHP information if a web-broker's non-Exchange website does not support enrollment in a QHP, except in cases where the web-broker's website is intended to be available for use by assisters consistent with proposed paragraph (c)(3)(iii)(A). In that case, the flexibility at new proposed paragraph (n) would not be available. A web-broker's non-Exchange website may not support enrollment in a QHP if the web-broker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances, we propose that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, web-brokers would be required to display the

¹¹⁹ See Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54069 at 54134 (August 30, 2013).

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following limited, minimum information for such QHPs: issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information. To take advantage of this new proposed flexibility, we also propose that the web-broker's non-Exchange website would be required to identify to consumers the QHPs, if any, for which the web-broker's website does not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange website, and includes a link to the Exchange website. We believe this proposal strikes an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. It also would minimize burdens for web-brokers by not requiring them to build functionality and processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for which they do not have an appointment to sell.

To more closely align the plan detail disclaimer text¹²⁰ with the intent of this proposal, we plan to issue further guidance revising the text of the disclaimer so that it can be clearly associated with any QHPs for which the web-broker website does not facilitate enrollment. For example, the current disclaimer text states, in relevant part, the web-broker "isn't able to display all required plan information about this Qualified Health Plan at this time." We are considering

¹²⁰ The current plan detail disclaimer states: "[Name of Company] isn't able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at HealthCare.gov." See also Section 5.3.2 of the "Federally-Facilitated Exchanges (FHEs) and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual." Available at https://www.regtap.info/uploads/library/ENR_FFEFFSHOPENrollmentManual2020_5CR_090220.pdf.

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modifying this text so that it states, in relevant part, the web-broker “doesn’t display all plan information about, and doesn’t facilitate enrollment in, this Qualified Health Plan at this time.”

We invite comments on the proposed required limited, minimum QHP details that must be displayed for those QHPs that the web-broker does not facilitate enrollment in through its non-Exchange website and the proposed edits to the plan detail disclaimer text. We also seek comment on whether to require display of any additional elements identified under § 155.205(b)(1) among the limited, minimum information, such as summaries of benefits and coverage.¹²¹

c. Web-broker Operational Readiness Review Requirements

We propose amendments to further clarify the operational readiness requirements applicable to web-brokers by adding a new proposed § 155.220(c)(6). In the 2018 Payment Notice final rule, we adopted rules to require web-brokers to demonstrate operational readiness, including compliance with applicable privacy and security requirements, prior to participating in the FFE direct enrollment program.¹²² Our intent in codifying this requirement was to build on the onboarding and testing processes for a web-broker to be approved to use the direct enrollment pathways. We noted the expectation that additional operational readiness requirements would be established specific to EDE to account for the additional functionality associated with that pathway.¹²³ At the same time, we established similar requirements for QHP issuers to demonstrate operational readiness and compliance with applicable requirements prior

¹²¹ Section 155.205(b)(1) references the following comparative QHP information: premium and cost-sharing information, the summary of benefits and coverage, metal level, results of enrollee satisfaction surveys, quality ratings, medical loss ratio information, transparency of coverage measures, and the provider directory.

¹²² See 81 FR 94176.

¹²³ See 81 FR 94120.

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to their use of the direct enrollment pathway.¹²⁴ In the 2020 Payment Notice, we consolidated these similar requirements from their prior locations at §§ 155.220(c)(3)(i)(K) and 156.1230(b)(2) into § 155.221(b)(4) as part of our effort to streamline requirements applicable to all direct enrollment entities.¹²⁵ In this rule, we propose to create a new proposed § 155.220(c)(6) to capture operational readiness requirements applicable to web-brokers that host non-Exchange websites to complete QHP selection or the Exchange eligibility application. In proposed paragraph (c)(6), we propose to include introductory language that reflects the requirement for a web-broker to demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in a form and manner specified by HHS, of certain information or testing processes. As reflected in proposed paragraphs (c)(6)(i) through (v), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes may include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with

¹²⁴ See 81 FR 94152.

¹²⁵ See 84 FR 17524.

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applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers will have to maintain and provide access to testing environments that reflect their prospective or actual production environments. We are proposing these amendments to codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.¹²⁶ We are not proposing to extend the same requirements to QHP issuers participating in the FFE direct enrollment program, because QHP issuers, as HIPAA-covered entities, are subject to longstanding federal requirements and oversight related to the protection of PII and PHI that are not necessarily applicable to web-brokers. With HIPAA privacy and security regulations and oversight in place and applicable to QHP issuers, HHS has adopted a risk acceptance approach for QHP issuers allowing them to participate in the FFE direct enrollment program, in some cases, without imposing certain requirements that are in place for web-brokers. In addition, QHP issuers are subject to more extensive oversight by state regulators than web-brokers.

We seek comment on this proposal.

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

a. Direct Enrollment Entity Plan Display Requirements

We propose to revise § 155.221(b)(1) to clarify the requirements that apply when direct enrollment entities want to display and market QHPs¹²⁷ and non-QHPs. We propose that in such

¹²⁶ See, for example, “Updated Web-broker Direct Enrollment Program Participation Minimum Requirements,” May 21, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf>.

¹²⁷ As detailed in prior rulemaking, with some limited exceptions, stand-alone dental plans certified for sale on an Exchange are considered a type of QHP. See 77 FR 18315. CMS expects direct enrollment entities to follow the

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circumstances, the web-broker or QHP issuer must display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain proposed exceptions described below.

In the 2020 Payment Notice, we amended § 155.221(b)(1) to require direct enrollment entities to display and market QHPs and non-QHPs on separate website pages on their respective non-Exchange websites.¹²⁸ We explained that this proposal was intended to balance the goals of minimizing consumer confusion about distinct products with substantially different characteristics, and providing direct enrollment entities marketing flexibility and opportunities for innovation.¹²⁹ Similarly, we amended paragraph (b)(3) to require direct enrollment entities to limit the marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that will minimize the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not.¹³⁰ Under the existing display standards captured at paragraphs (b)(1) and (3), direct enrollment entities are required to offer an Exchange eligibility application and QHP selection process that is free from advertisements or information about non-QHPs and sponsored links promoting health insurance related products. However, under the current framework, it is permissible for a direct enrollment entity to market or display non-QHP health plans and other off-Exchange products in a section of the entity's website that is separate from the QHP web pages if the entity otherwise complies

same requirements for stand-alone dental plan QHPs as for medical QHPs, including the applicable display and marketing requirements captured in §§ 155.220, 155.221 and 156.1230, except as proposed at new § 155.221(c)(2) in the context of off-Exchange stand-alone dental plan shopping.

¹²⁸ See 84 FR 17523 and 17524.

¹²⁹ See 84 FR 17523.

¹³⁰ Id.

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with the applicable requirements. We explained in the 2020 Payment Notice that we believe marketing some products in conjunction with QHPs may cause consumer confusion, especially as it relates to the availability of financial assistance for QHPs purchased through the Exchanges.¹³¹ We acknowledged at that time that we may need to update these standards as new products come to market and as technologies evolve that can assist with differentiating between QHPs offered through the Exchange and other products consumers may be interested in. We also noted our belief that the convenience of being able to purchase additional products as part of a single shopping experience outweighs potential consumer confusion, if proper safeguards are in place.¹³²

We propose to amend paragraph (b)(1) to refine the previously adopted policy, consistent with the original intent of minimizing consumer confusion about distinct products with substantially different characteristics, while providing direct enrollment entities with more marketing flexibility and opportunities for innovation. QHPs are required to be offered on- and off-Exchange under the guaranteed availability requirements at § 147.104. The current framework allows for direct enrollment entities to display on- and off-Exchange QHPs on the same website pages, as long as the direct enrollment entity's website makes clear that APTC and CSRs are only available for QHPs offered through the Exchange.¹³³ We have observed various attempts by direct enrollment entities to distinguish between on- and off-Exchange QHPs displayed on the same website pages, but believe that even good faith efforts to inform consumers about this distinction have the potential to cause confusion about which QHP a consumer should select if APTC-eligible when two instances of otherwise identical plans (that is,

¹³¹ Id.

¹³² Id.

¹³³ See, for example, 45 CFR 155.220(j)(2)(i) and 156.1230(a)(1)(iii).

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the on- and off-Exchange versions of the QHP) are displayed on a single website page, but only one is available with APTC. In addition, paragraph (b)(1) currently prohibits the display of off-Exchange QHPs on the same website pages as comparable non-QHP individual health insurance coverage. This creates a segmented off-Exchange plan shopping experience on direct enrollment entity websites that does not allow consumers to easily comparison shop among comparable major medical health insurance products. As described further below, the recent introduction of individual coverage HRAs increases the importance of individual health insurance coverage offered outside of the Exchange for employees whose employers offer such arrangements and also offer the opportunity to make salary reduction contributions through a cafeteria plan under section 125 of the Code, and this is part of the reason we are considering amending the current display requirements for direct enrollment entities.

We propose to revise § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. Requiring that these three categories of products be displayed and marketed on separate website pages provides a more precise delineation between the three categories of products with substantially different characteristics, either in the way they can be purchased or the types of benefits they offer, while still allowing substantial flexibility in website design to facilitate the consumer's shopping experience. We propose the first product category, QHPs offered through the Exchange, must be isolated from the other categories of products to distinguish for consumers the products for which APTC and CSRs are available (if eligible). We propose the second product category, individual health insurance coverage offered outside the

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Exchange (including QHPs and non-QHPs other than excepted benefits), must be similarly distinguished from other products, because those plans represent major medical coverage that is subject to the same PPACA market-wide requirements as QHPs offered through the Exchange, but that is not available with APTC and CSRs. Therefore, distinguishing between these two categories of products by requiring that they be displayed and marketed on separate website pages will allow consumers to more easily shop for comparable major medical insurance subject to PPACA market-wide rules while maintaining the clear distinction between plans for which APTC and CSRs are and are not available. We propose that the third product category, which encompasses types of products not in the first two categories, including excepted benefits, must be displayed and marketed on one or more website pages separate from the website pages used for displaying and marketing the first two categories of products to assist consumers in distinguishing them from major medical plans. The range of products in the third category are not subject to PPACA market-wide rules and APTC and CSRs are not available with such products, and therefore they are substantially different from the plans that fall into the first two categories.

We also propose to amend § 155.221(b)(3) to include clarifying edits and to include the same exceptions detailed below as we are proposing for paragraph (b)(1). We propose to revise paragraph (b)(3) to limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under new proposed paragraph (c)(1). This proposal removes a redundant reference to “plan” that was included after “QHP,” and adds references to “plans” after the references to “products” to use consistent language throughout paragraphs

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(b)(1) and (3). We are proposing the same exceptions for paragraph (b)(3) to align with the proposed changes to paragraph (b)(1) to clarify that displaying QHPs and non-QHPs on the same website page, as would be permitted under the proposed exceptions in certain circumstances, would not constitute a violation of paragraphs (b)(1) or (3).

We propose certain exceptions in new § 155.221(c) to the proposed updates to paragraphs (b)(1) and (3), because we recognize that, in some limited scenarios, consumers may be best served by being able to directly and easily compare plans offered on- and off-Exchange. As of January 1, 2020, employers may offer employees an individual coverage HRA (health reimbursement arrangement) instead of offering traditional group health coverage.¹³⁴ An individual coverage HRA may reimburse employees for medical expenses, including monthly health insurance premiums. To use the individual coverage HRA, an employee (and any eligible household members) must enroll in individual health insurance coverage, other than excepted benefits, or Medicare parts A and B or C. To satisfy this requirement, employees (and any eligible household members) can enroll in individual health insurance coverage through the Exchange or outside the Exchange. An employee and any household members offered an individual coverage HRA will be ineligible for APTC if the individual coverage HRA is affordable or if the employee and household members accept the individual coverage HRA even if it is unaffordable. If an employee and any household members offered an individual coverage HRA that is unaffordable decline the individual coverage HRA benefit, they may qualify for APTC (if otherwise eligible) if they enroll in a QHP through the Exchange. Some employees who are offered an individual coverage HRA may also be eligible, through a cafeteria plan under

¹³⁴ See Health Reimbursement Arrangements and Other Account-Based Group Health Plans; Final rule, 84 FR 28888 (June 20, 2019).

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section 125 of the Code, to pay a portion of their health insurance premiums through tax-preferred salary reduction contributions. This type of cafeteria plan benefit may only be used in combination with off-Exchange individual health insurance coverage. Employers have flexibility to offer an employee both the individual coverage HRA and the cafeteria plan benefit instead of providing traditional tax-preferred group health coverage. However, employers may not offer employees a choice of an individual coverage HRA or traditional group health coverage.

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

In proposed new paragraph (c)(1), we propose to allow direct enrollment entities to display and market QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated, within the website user interface or by communicating to an agent or broker assisting them, they have received an offer of an individual coverage HRA, as a standalone benefit or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for

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individual health insurance coverage that is not covered by an individual coverage HRA using a salary reduction arrangement under a cafeteria plan, so long as certain conditions are met. As reflected in the new proposed § 155.221(c)(1), the conditions we propose to adopt include clearly distinguishing between the QHPs offered through the Exchange and the individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicating that APTC and CSRs are available only for QHPs purchased through the Exchange, that APTC is not available to an individual who accepts an offer of an individual coverage HRA or who opts out of an affordable individual coverage HRA, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange.

In addition, we wish to reduce incentives that may lead to routing consumer households to off-Exchange plan shopping experiences based on overly simplistic factors such as a single member of a multi-member household having an individual coverage HRA and a cafeteria plan offer. Instead we seek to encourage direct enrollment entities to develop blended plan selection user interfaces that incorporate on- and off-Exchange plan options when assisting consumers who have communicated receipt of an offer of an individual coverage HRA while incorporating the proposed conditions that are designed to minimize the chance for consumer confusion about the differences between the different coverage options. For example, a direct enrollment entity exercising the flexibility under the proposed exception in § 155.221(c)(1) could clearly distinguish between on- and off-Exchange plan options by using frames, columns, different color schemes, prominent headings, icons, help text, and other visual aids to increase the chance that consumers are aware of the distinctions between the plan options. We emphasize the proposal's intent is for distinguishing and clarifying user interface elements to be clear, prominent, and

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difficult to ignore, and therefore the use of an obscure disclaimer in small text at the bottom of the page or behind a link would not be sufficient, for example. We note that in addition to the safeguards proposed in this rule, direct enrollment entities in the FFEs are subject to standards of conduct that require they provide consumers with correct information, without omission of material fact, regarding QHPs and insurance affordability programs, and refrain from marketing or conduct that is misleading.¹³⁵ We solicit comment on these proposals, as well as comments on alternative approaches through which direct enrollment entities may assist consumers with individual coverage enrollment when they have an offer of an individual coverage HRA.

We propose an additional exception to § 155.221(b)(1) at proposed paragraph (c)(2) to allow direct enrollment entities to display and market stand-alone dental plans certified by an Exchange but offered outside the Exchange and non-certified stand-alone dental plans on the same off-Exchange dental plan shopping website pages. Stand-alone dental plans certified by an Exchange and non-certified stand-alone dental plans should be largely comparable products among which consumers looking for dental coverage off-Exchange may wish to comparison shop. Since the proposed change at paragraph (b)(1) to allow display of all individual health insurance coverage offered outside the Exchange on the same website pages (including QHPs and non-QHPs other than excepted benefits) excludes stand-alone dental plans (since stand-alone dental plans are excepted benefits), we propose this additional exception to allow direct enrollment entities to provide a consumer-friendly off-Exchange stand-alone dental plan

¹³⁵ See 45 CFR 155.220(j)(2)(i), applicable to web-brokers, and 156.1230(b)(2), applicable to QHP issuers participating in direct enrollment. Also see “Guidance Regarding Website Display for Direct Enrollment (DE) Entities Assisting Consumers in States with Federally-facilitated Exchanges (FFE) and State-based Exchanges on the Federal Platform (SBE-FPs).” Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/DE-Entity-Standards-of-Conduct-Website-Display.pdf>.

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shopping experience where consumers can compare the full range of stand-alone dental plans on a single website page.

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

We request comment on these proposals.

b. Direct Enrollment Entity Operational Readiness Review Requirements

We propose to revise § 155.221(b)(4) to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new proposed § 155.220(c)(6), we are proposing these amendments to codify in § 155.221(b)(4) more details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We note that these proposed requirements are in addition to the operational readiness requirements for web-brokers at new proposed § 155.220(c)(6), although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in the direct enrollment program and the source and type of documentation. For example, a web-broker seeking to participate only in the Classic DE program would only be required to meet the operational readiness requirements at new proposed § 155.220(c)(6), whereas a web-broker seeking to participate in the EDE program may be permitted to use its third-party security and privacy audit documentation for EDE to satisfy

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the security and privacy audit documentation requirements of §§ 155.220(c)(6) and 155.221(b)(4) assuming the Classic DE and EDE systems and functionality were hosted in the same environments subject to the third-party audit.

In paragraph (b)(4), we propose to continue to require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We add new proposed paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit or complete, in the form and manner specified by HHS, a number of artifacts, documentation, or various testing or training processes. The documentation may include business audit documentation, including: notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results. Submission of agreements between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program may also be required. Required testing may include eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in the direct enrollment program.

We request comment on this proposal.

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c. FFE, SBE-FP, and State Exchange Direct Enrollment Options

While CMS has taken a number of actions to reduce the burden on states in establishing State Exchanges, CMS wishes to maximize flexibility for all states to oversee their own healthcare markets and to address unique market dynamics in each state. As explained in the Exchange Establishment Rule, we recognize that states are best equipped to adapt the minimum Exchange functions to their local markets and the unique needs of their residents.¹³⁶ In addition, CMS recognizes that for decades, issuers, licensed agents and brokers, and web brokers have been engaging directly with consumers in offering health insurance and assisting consumers in selecting, enrolling in, and managing their coverage. In light of the success of the FFEs' classic direct enrollment and EDE pathways, which permit approved issuers and web brokers to facilitate enrollment in QHPs offered through the FFEs and SBE-FPs using non-Exchange websites, CMS is proposing to provide additional options for states that wish to promote more flexible and lower cost private-sector approaches for assisting consumers with shopping and enrolling in QHP coverage offered through Exchanges. We believe that this proposal also would allow states to continue to more effectively exercise their traditional oversight authority over health insurance markets, while enhancing the consumer experience, increasing competition, and lowering costs.

To date, Exchange application and enrollment activities have been supported through Exchange-operated websites. One of the primary advantages of this design is that consumers can access one-stop shopping for all QHPs offered through an Exchange and can access relevant details on such plans in a standardized format. Before Exchanges existed, consumers shopping for individual market health insurance who tried to search for this information would have to

¹³⁶ See, for example, 77 FR at 18313.

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contact multiple issuers or visit multiple web sites, and the information would often be presented inconsistently, preventing true apples-to-apples comparison shopping. Exchange-run application and enrollment websites also help to manage churn between private health insurance coverage and public programs such as Medicaid and CHIP by offering connections to those public programs for individuals who may qualify for participation.

While Exchange-operated application and enrollment websites have undoubtedly helped many consumers shop for and compare plans, they also present some significant potential disadvantages given historical and current implementation. First, it can be costly and burdensome to create and operate Exchanges, including not only the cost of designing and maintaining a complex website, but also the burden of staffing and operation of call centers that must be scaled up during each annual Open Enrollment Period (OEP), and then scaled down during lower-traffic periods. Second, the design of Exchange-operated websites also tends to result in choke points when a large number of consumers use the same website at the same time to shop for and enroll in coverage. For example, on high traffic days near the end of the annual OEP, some consumers trying to access HealthCare.gov have been redirected to the FFE call center or told to come back to the website at a later time to complete their enrollment due to volume, resulting in missed enrollment opportunities for some consumers. We have experienced issues with consumer facing (front-end) functions inhibiting consumer access to enrollment on HealthCare.gov while consumers are still able to shop for coverage through EDE and DE partners that rely on federal supporting functions (back-end), such as the processing of data matching and special enrollment period verification documentation, casework, and eligibility appeals. Although we recognize that without robust competition among EDE and DE partners,

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an EDE or DE partner's website may experience similar choke points due to high consumer traffic, state's flexibility to partner with more than one DE or EDE entity mitigates this risk.

Third, we believe it is inherently difficult for Exchanges to keep up with the rapid pace of innovation in e-commerce and the ever-evolving preferences of online shoppers, who are accustomed to shopping for the products they buy in a manner that is not only tailored to their specific needs, but is also aesthetically appealing and constantly refreshed. Federal contracting rules, for example, may limit the government's ability to frequently refresh and update the consumer experience. Finally, we have heard criticisms from some stakeholders that the Exchange-operated application and enrollment website model competes directly with and may crowd out market players such as web brokers, licensed agents and brokers, and issuers, dampening commercial investments in outreach and marketing by these market players to reach new consumers.

We believe that both the FFE's classic direct enrollment and EDE pathways have promoted innovation and competition in states using the HealthCare.gov platform and have ultimately lead to better experiences for consumers in these states. Direct enrollment, which has been in operation since the launch of the Exchange in 2013, and enhanced direct enrollment, which has been in operation since 2018, together are responsible for one-third of FFE enrollments. Today, the Healthcare.gov application and enrollment website and approved private sector non-Exchange websites operate side-by-side to enroll consumers in individual market QHPs offered through the FFEs and SBE-FPs. Like Exchange-operated websites, non-Exchange websites operated by direct enrollment partners in these states are required to provide standardized comparative information to assist consumers shopping for coverage.¹³⁷ Unlike FFE

¹³⁷ See, for example, 45 CFR 155.220(c)(3)(i)(A) (for web-brokers) and 156.1230(a)(1)(ii) (for QHP issuers).

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and SBE-FP application and enrollment websites, private sector entities, including those who participate in the FFE's classic and EDE pathways, are also able to provide assistance with a broader array of plan options, including both on- and off-Exchange plan options and ancillary products. This is an important feature for many consumers who do not qualify for PTCs due to their income, employees with an offer of an affordable individual coverage HRA, as well as employees offered both an individual coverage HRA and a cafeteria plan because the Code specifically prohibits using salary reduction contributions under a cafeteria plan to purchase on-Exchange coverage.¹³⁸ Finally, the FFE's EDE pathway helps to reduce costs to the federal government by enrolling many consumers without touching the FFEs' application intake and enrollment resources (for example, the Marketplace call center and the HealthCare.gov website).

To build on the success of the FFE's classic direct enrollment and EDE pathways for FFE and SBE-FP states that use HealthCare.gov, and to offer additional flexibility to all states, we are proposing a new opportunity for states to adapt the minimum Exchange functions to their local markets and leverage the benefits of direct enrollment to enhance the consumer experience through a private sector-focused consumer engagement and enrollment strategy. We propose to add § 155.221(j) to establish a process for states to elect a new Exchange Direct Enrollment (DE) option in which a state can request to allow private sector entities (including QHP issuers, web-brokers, agents and brokers) to operate enrollment pathways through which consumers can apply, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with APTC and CSRs, if otherwise eligible.

¹³⁸ As detailed above there is a growing cohort of consumers who may be interested in off-Exchange coverage options.

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As outlined in proposed § 155.221(j), subject to HHS approval, a state may elect for its Exchange to engage one or more entities described in paragraph (a)¹³⁹ to facilitate QHP enrollments through the Exchange. Under this option, similar to the current FFE direct enrollment program, the approved direct enrollment entities would enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange¹⁴⁰ and would also assist individuals in applying for and receiving eligibility determinations from the Exchange for APTC and cost-sharing for QHPs offered through the Exchange.

New proposed § 155.221(j)(1) outlines proposed requirements that would apply to State Exchanges that do not rely on the federal eligibility and enrollment platform that want to pursue the SBE-DE option. New proposed paragraph (j)(2) outlines proposed requirements that would apply to states with an FFE or SBE-FP¹⁴¹ that want to pursue the FFE-DE or SBE-FP-DE option. We propose that, subject to HHS approval, the SBE-DE option may be implemented in states with a State Exchange starting in plan year 2022. We propose that, subject to HHS approval, the FFE-DE and SBE-FP-DE option may be implemented in states with an FFE or SBE-FP starting in plan year 2023.

¹³⁹ Section 155.221(a) identifies QHP issuers and web-brokers as eligible direct enrollment entities.

¹⁴⁰ Section 1401(a) of the PPACA added new section 36B to the Code, which provides for PTCs for eligible individuals, while section 1402 of the PPACA provides for CSRs for eligible individuals. For individuals to be eligible to receive PTCs, among other requirements, the PPACA requires that individuals be enrolled in a QHP through an Exchange. CMS has interpreted this statutory language to allow a QHP issuer to enroll an applicant who initiates enrollment directly with the QHP issuer. See § 156.1230, whereby individuals enrolling directly on the site of a QHP issuer are considered enrolled “through an Exchange” so long as the issuer meets applicable requirements. We adopted a similar approach to allow a web broker to enroll an applicant who seeks to enroll through the web broker’s website. See § 155.220(a)(2) and (c), whereby individuals enrolling directly through the site of a web broker are considered enrolled “through an Exchange” so long as the web broker meets applicable requirements.

¹⁴¹ As detailed further below, states with an SBE-FP can request to pursue the DE option as an SBE-FP-DE. If a state that currently operates an SBE-FP is interested in transitioning to a full State Exchange that implements this DE option, it would need to update its Blueprint accordingly, and meet statutory and regulatory requirements to become a State Exchange implementing the DE option (an SBE-DE). Such requirements include operating its own eligibility and enrollment platform rather than relying on the federal platform.

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Under each of the Exchange DE options, states would be able to request to adopt a private sector-based enrollment approach as an alternative to the Exchanges' consumer-facing enrollment website (for example, HealthCare.gov for the FFEs). This less centralized, private sector-focused approach for enrollment would transition to websites operated by approved partners to serve as the online platform(s) through which consumers apply for and enroll in individual market QHPs offered through the Exchange in their state, as well as apply for and receive determinations of APTC and CSR eligibility for QHP coverage offered through the Exchange. An Exchange would implement a direct enrollment pathway (or pathways) with secure connections between its back-end eligibility system and the systems of approved issuers, web brokers, or agents and brokers that enable consumers to complete the single streamlined eligibility application as described in § 155.405, receive an eligibility determination from the Exchange, select a plan and enroll in a QHP, with or without APTC and CSRs (if otherwise eligible). Exchanges would continue to be responsible for meeting, and ensuring its approved direct enrollment partners meet, all applicable statutory and regulatory requirements governing application for and enrollment in QHPs. Under these DE options, the Exchange would also remain the entity responsible for making eligibility determinations, conducting required verifications of consumer application information, and determining whether an applicant is eligible for QHPs, APTCs, and CSRs. The Exchange would also continue to be responsible for sharing this information with CMS, which will continue to issue the applicable APTC to carriers on behalf of qualified individuals, and to the IRS, which will continue to administer the reconciliation of APTC on individual tax returns. Consistent with section 1311(d)(4)(F) of the PPACA and 45 CFR 155.302, under these DE options the Exchange would also continue to be responsible for conducting assessments or determinations of eligibility for Medicaid and CHIP,

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and refer such individuals to the appropriate state Medicaid agency for enrollment in such program(s).¹⁴²

In proposing these options for states, we note that the applicable statutory provisions do not require either the federal government or states to operate an enrollment website. Rather, the PPACA provides that an Exchange must, at a minimum, certify plans as QHPs and make QHPs available to consumers, and facilitate the purchase of QHPs. An Exchange can continue to meet these obligations and the minimum functions outlined in the statute without operating a singular consumer-facing enrollment website. In the context of operating an internet website, we interpret the statutory language at section 1311(c)(5) and (d)(4)(C) of PPACA to require the Exchange provide consumers with the ability to view comparative information on QHP options but that the Exchange may direct consumers to other entities or resources for purposes of submitting applications for and enrolling in QHPs, with APTC and CSRs, if otherwise eligible. Exchanges in states that elect to pursue this new option would be required to continue to grant exemption certifications under section 1311(d)(4)(H) of the PPACA, as applicable; make available an electronic calculator consistent with section 1311(d)(4)(G) of the PPACA; establish a Navigator program as required under section 1311(d)(4)(K) of the PPACA; and provide for the operation of a toll-free telephone hotline under section 1311(d)(4)(B) of the PPACA.

For the FFE-DE, SBE-FP-DE, and SBE-DE options, the Exchange would make available both a basic website listing basic QHP information for comparison and a listing, with links, to approved partner websites for consumer shopping, plan selection, and enrollment activities.

Consistent with section 1311(d)(4)(E) of the PPACA, the comparative plan information

¹⁴² Section 1311(d)(4)(F) requires Exchanges to inform individuals of eligibility requirements for Medicaid, CHIP, or any applicable State or local public programs and, if through screening of the application the Exchange determines such individuals are eligible for any such program and refer such individuals to the appropriate state Medicaid agency for enrollment in such program(s).

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presented on the Exchange website would need to continue to utilize a standardized format, including the use of the uniform summary of benefits and coverage outline of coverage established under section 2715 of the PHS Act.¹⁴³ The standardized comparative information displayed on Exchange websites must also continue to include the quality ratings assigned to each QHP offered through the Exchange.¹⁴⁴ Through private sector partners such as web-brokers and issuers, states may pursue alternatives to HealthCare.gov or other centralized, state-operated Exchange enrollment websites to enhance the consumer experience and provide additional incentives for insurers and licensed agents and brokers to conduct marketing and outreach to enroll more consumers in coverage. While states may consider creating enhanced commission structures or providing other market-based incentives, we also recognize the inherent incentive to issuers, web brokers, and agents and brokers that will result from removing what some stakeholders view as a dominant public-sector competitor, making them the primary channels through which individuals shop for and enroll in individual market QHPs in that state. We further recognize that consumers who apply and enroll through a direct enrollment pathway will have the benefit of assistance from a state-licensed agent or broker if they so choose. These agents and brokers will have been recognized by the relevant state as possessing the specialized expertise necessary to help consumers choose between health insurance options. We propose three options for states to pursue the new Exchange DE option as described more fully below. We also note that the proposed new flexibilities in §§ 155.205(c)(2)(iv)(B) and (C), as well as in § 155.220(n), would need to be coordinated and considered as part of a state's request to transition to the applicable Direct Enrollment option to determine to what extent these

¹⁴³ See 45 CFR 155.205(b).

¹⁴⁴ See section 1311(d)(5)(D) of the PPACA and 45 CFR 155.205(b). Also see sections 1311(c)(3) and (c)(4) of the PPACA and 45 CFR 155.1400 and 1405.

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flexibilities may be made available to web-brokers approved to begin operating in an SBE-DE, FFE-DE, or SBE-FP-DE states, as proposed in § 155.221(j). For example, per requirements imposed through the Exchange Blueprint,¹⁴⁵ any State Exchange interested in pursuing this option would need to show that there would be at least one website available in the State that satisfies all accessibility requirements under § 155.205(c). Such website could be the State Exchange's consumer-facing website, or a website operated by a State Exchange-approved direct enrollment entity.

(1) Federally-Facilitated Exchange Direct Enrollment (FFE-DE) and State Exchange on the Federal Platform Direct Enrollment (SBE-FP-DE) Options

We propose an option for any FFE or SBE-FP state to request the use of direct enrollment as the enrollment avenue through which individual market consumers and qualified individuals can shop for and purchase a QHP offered through the Exchange in the state and apply and receive determinations of eligibility for APTC and CSRs. While SBE-FP states have the authority and responsibility for certifying QHPs and performing consumer outreach and assistance activities, because they rely on the HealthCare.gov eligibility and enrollment platform and website, in this respect they are more similar to the FFE-DE model than the SBE-DE model. In addition, the current FFE direct enrollment program and accompanying requirements also apply in SBE-FP states.¹⁴⁶

Under the proposed FFE-DE and SBE-FP-DE options, HealthCare.gov would continue to provide the same standardized comparative information on QHP options that is available today. CMS also would post and maintain an up-to-date list on HealthCare.gov of approved direct

¹⁴⁵ See Blueprint for Approval of State-based Health Insurance Exchanges for Coverage Years Beginning on or after 2019, available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CMS-Blueprint-Application.pdf>.

¹⁴⁶ See, for example, 45 CFR 155.220(l) and 155.221(h).

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enrollment partners operating in the state. As such, consumers would still be able to view comparative information on HealthCare.gov for all QHP options available in their area and would also be able to access information to connect with approved direct enrollment partners in that state. Additionally, in the event that any approved direct enrollment partner does not have the technical capability to handle a consumer application, HealthCare.gov would process that application.

By leveraging private sector entities and directing consumers to approved direct enrollment partners, the vast majority of consumer traffic would flow to direct enrollment partners, leaving the HealthCare.gov structure in place primarily to provide the supporting functions that it does today, like the processing of data matching and special enrollment period verification documentation, casework, and eligibility appeals.

As noted above, the Exchange would remain the entity responsible for making eligibility determinations and validating if an applicant is eligible for QHPs, APTCs and CSRs. The Exchange would also continue to issue the applicable APTC to carriers on behalf of qualified individuals and would share the relevant information with the IRS to facilitate the IRS' reconciliation of APTC on individual tax returns. Under this option, given that an FFE-DE state or SBE-FP-DE state would use one or more participating, federally-approved DE and EDE partners, at a minimum, the FFE privacy and security standards¹⁴⁷ and the FFE direct enrollment requirements¹⁴⁸ would continue to apply.

As outlined in new proposed § 155.221(j)(2), a state with an FFE or SBE-FP may request to pursue the FFE-DE or SBE-FP-DE option, as applicable. As outlined in this new proposed

¹⁴⁷ See 45 CFR 155.260, et. seq.

¹⁴⁸ See 45 CFR 155.220, 155.221, and 156.1230.

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regulation, pursuant to a request from the state, HHS may partner with the requesting state to implement the direct enrollment option described in paragraph (j)(1). The FFE or SBE-FP must meet all applicable federal statutory and regulatory requirements for the operation of an Exchange, including maintaining the single, streamlined application required under § 155.405. In order to obtain HHS approval to implement this option, the state must coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the state, necessary to operationalize the required changes to implement this option. We propose to codify these new requirements at paragraph (j)(2)(i). Additionally, we propose to codify requirements at paragraph (j)(2)(ii), whereby the state must execute a federal agreement with HHS that includes the terms and conditions for the arrangement and which defines the division of responsibilities between HHS and the state. Further, in order to obtain HHS approval to implement the FFE-DE or SBE-FP-DE option, the state must agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) in support of the responsibilities undertaken by the state and HHS. We propose to codify this new requirement at § 155.221(j)(2)(iii). Finally, we propose that the state would be required to perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of the PPACA, including complying with reporting and compliance activities required by HHS and described in the Federal agreement entered into pursuant to paragraph (j)(2)(ii). We propose to codify this new requirement at paragraph (j)(2)(iv).

We request comment on all aspects of this proposal, including any comments related to timing, governance, and any other considerations needed to effectively operationalize this proposed option.

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(2) State Exchange Direct Enrollment Option (SBE-DE)

Under the SBE-DE option, a state with a State Exchange that does not rely on the federal eligibility and enrollment platform can also elect the Exchange Direct Enrollment option to engage approved private-sector entities as the pathway for consumers in their state to apply for, and enroll in, QHPs offered through the Exchange. Under this proposed option, the State Exchange would remain responsible for continuing to operate its eligibility platform and make eligibility determinations for consumers applying for APTC, CSRs and enrollment in QHPs offered through the Exchange. However, this new option would permit multiple private entities, such as a combination of web-brokers and issuers, to provide the consumer-facing resources for consumers to apply for and enroll in individual market coverage offered through the Exchange. State Exchanges that pursue this option could thereby leverage direct enrollment technology and direct consumers to approved partner non-Exchange websites to apply for APTC and CSRs, as well as select and enroll in a QHP offered through the Exchange (if otherwise eligible). In the event that no direct enrollment partner in the state has the technical capability to handle any consumer's application, the State Exchange would need to have the capability to process that application through its own consumer-facing website.

As outlined in new proposed § 155.221(j)(1), a state with a State Exchange that does not rely on the federal eligibility and enrollment platform may request approval to pursue the SBE-DE option and must submit a revised Exchange Blueprint in accordance with § 155.105(e) to do so.¹⁴⁹ As outlined in this new proposed regulation, the State Exchange must meet all other

¹⁴⁹ This approach is consistent with the framework established in prior rulemakings that require a state to notify HHS and receive written approval from HHS before significant changes are made to the Exchange Blueprint. See, for example, 77 FR at 18316. Significant changes could include altering a key function of Exchange operations or other changes to the Exchange Blueprint that would have an impact on the operation of the Exchange. This includes, but is not limited to the process for enrollment in a QHP. See, for example, 76 FR at 41871.

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applicable federal statutory and regulatory requirements for the operation of an Exchange, including maintaining the single, streamlined application as described in § 155.405. Following submission of the revised Blueprint, HHS would have up to a total of 90 days¹⁵⁰ to review this revised submission and render a decision as to approval. We propose to codify the new requirement at § 155.221(j)(2)(ii) that, in order to obtain HHS approval, the state would need to provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities. States that want to pursue the SBE-DE option should coordinate with HHS early in the development process and would be encouraged to provide the implementation plan, timeline and outreach strategy in advance of the formal submission of the state's revised Exchange Blueprint. Additionally, in accordance with § 155.105(c)(2) and the new requirement proposed at § 155.221(j)(1)(ii), a transitioning SBE-DE would need to demonstrate to HHS operational readiness for the State Exchange and its proposed direct enrollment entities to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and to enable individuals to apply for APTC and cost sharing for QHPs.

While we propose that SBE-DEs would retain the flexibility to determine their own business controls, as well as to decide the state-specific requirements and mechanisms for approval and oversight of direct enrollment entities operating in the state, we would encourage SBE-DEs to generally review and adopt processes and standards similar to the existing federal direct enrollment and EDE framework, as laid out at 45 CFR 155.220, 155.221, 156.1230, and in

¹⁵⁰ As detailed in § 155.105(e), HHS generally has 60 days after receipt of a completed request to complete its review of a significant change to an Exchange Blueprint and, for good cause, may extend the review period by an additional 30 days up to a total of 90 days.

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subregulatory guidance.¹⁵¹ Moreover, we propose to codify a new requirement at § 155.221(j)(1)(iii) whereby SBE-DEs are obligated to ensure that a minimum of one approved direct enrollment entity approved by the state meets the minimum federal requirements for HHS approval to participate in the FFE federal direct enrollment programs, including requirements at 45 CFR 155.220 and 155.221. In particular, it is critical that the SBE-DE ensure at least one approved web-broker direct enrollment partner or other approved direct enrollment entity meets requirements that align with the FFE standards under 45 CFR 155.220(c)(3)(i)(A) and (D)¹⁵² to ensure consumers have at least one option through which to view and access enrollment to all available QHPs in the state. It is also critical that the SBE-DE ensure at least one direct enrollment partner meets accessibility requirements under 45 CFR 155.205(c). If no direct enrollment in the SBE-DE states meets these requirements, the state would need to continue to operate its own Exchange website to ensure there is one enrollment pathway in the state that does. To assist states in meeting requirements for the SBE-DE option, we note that states would have the flexibility to partner with an existing, HHS-approved web-broker direct enrollment partner as a starting point to develop their own direct enrollment programs, as they are already fully-compliant with applicable federal requirements to participate in the FFE program.

We request comment on all aspects of this proposal, including any comments related to timing, governance, and any other considerations needed to effectively operationalize this option.

6. Certified Applications Counselors (§ 155.225)

¹⁵¹ See generally CMS guidance for becoming a web-broker in the FFEs, available at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/HealthInsurance-Marketplaces/Downloads/Processes-Becoming-Web-broker.pdf>.

¹⁵² As noted above, the proposed new flexibilities in §§ 155.205(c)(2)(iv)(B) and (C), as well as in § 155.220(n), would need to be coordinated and considered as part of a state's request to transition to the applicable Direct Enrollment option. In addition to ensuring there is at least one website available in the State that satisfies all accessibility requirements under § 155.205(c), we propose there must also be at least one website available in the State through which consumers can view and enroll in all available QHPs in the state.

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We propose to allow, but not require, certified application counselors to assist consumers with applying for eligibility for insurance affordability programs an QHP enrollment through web-broker websites under certain circumstances. For a discussion of the provisions of this proposal, please see the preamble for § 155.220.

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

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 and premium assistance (APTC or CSR) are requested using available data sources, if applicable, as described in § 155.320(d)(2). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in paragraph (d)(2)(i) through (iii), an alternate procedure applies. Specifically, Exchanges must select a statistically significant random sample of applicants and meet the requirements under paragraph (d)(4)(i). For benefit years 2016 through 2019, Exchanges also could use an alternative process approved by HHS. We are continuing to explore a new alternative approach to replace the current procedures in paragraph (d)(4)(i), under which an Exchange may design its verification process to confirm that qualified individuals are not eligible for or enrolled in an eligible employer sponsored plan, disqualifying them from receiving APTC or CSRs.

HHS's experience conducting random sampling revealed that employer response rates to HHS's request for information were low. The manual verification process described in § 155.320(d)(4)(i) requires significant resources and government funds, and the value of the results ultimately does not appear to outweigh the costs of conducting the work because only a

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small percentage of sample enrollees have been determined by HHS to have received APTC or CSRs inappropriately. We believe an approach to verifying an applicant's attestation regarding access to eligible employer sponsored coverage should be rigorous, while posing the least amount of burden on states, employers, consumers, and taxpayers. Based on our experiences with random sampling methodology under paragraph (d)(4)(i), HHS is of the view that this methodology may not be the best approach for all Exchanges to assess the associated risk for inappropriate payment of APTC and CSRs. As such, in 2019, HHS conducted a study to (1) determine the unique characteristics of the population with offers of employer-sponsored coverage that meets minimum value and affordability standards, (2) compare premium and out-of-pocket costs for consumers enrolled in affordable employer-sponsored coverage to Exchange coverage, and (3) identify the incentives, if any, that drive consumers to enroll in Exchange coverage rather than coverage offered through their current employer. We are still evaluating the results of this study to ensure the best verification process to ensure that consumers with offers of affordable coverage that meets affordability and minimum value standards through their employer are identified and do not receive APTC or CSRs inappropriately. HHS will consider changes to the verification process outlined under paragraph (d)(4) as part of future rulemaking.

As HHS continues to explore the best options for verification of employer sponsored coverage, we will continue to refrain from taking enforcement action against Exchanges that do not perform random sampling as required by paragraph (d)(4) and will extend this non-enforcement posture from plan year 2021 through plan year 2022.

8. Special Enrollment Periods (§ 155.420)

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a. Exchange Enrollees Newly Ineligible for APTC

We are proposing to add new flexibility to allow current Exchange enrollees and their dependents to enroll in a new QHP of a lower metal level¹⁵³ if they qualify for a special enrollment period due to becoming newly ineligible for APTC. In 2017, the Marketplace Stabilization Rule addressed concerns that Exchange enrollees were utilizing special enrollment periods to change plan metal levels based on ongoing health needs during the coverage year, negatively affecting the individual market risk pool. The Market Stabilization Rule set forth requirements at § 155.420(a)(4) to limit Exchange enrollees' ability to change to a QHP of a different metal level when they qualify for, or when a dependent(s) newly enrolls in Exchange coverage through, most types of special enrollment periods.¹⁵⁴

Generally, § 155.420(a)(4) provides that enrollees who newly add a household member through most types of special enrollment periods may add the household member to their current QHP or enroll them in a separate QHP,¹⁵⁵ 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

¹⁵³ Section 1302(d) of the PPACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the PPACA. Consumer-facing HealthCare.gov content explains that metal levels serve as an indicator of “how you and your plan split the costs of your health care,” noting that lower levels such as bronze plans have lower monthly premiums but higher out of pocket costs, while higher levels such as gold plans have higher monthly premiums but lower out of pocket costs. See <https://www.healthcare.gov/choose-a-plan/plans-categories/>.

¹⁵⁴ These limitations do not apply to enrollees who qualify for certain types of special enrollment periods, including those under § 155.420(d)(4), (8), (9), (10), (12), and (14). While special enrollment periods under paragraphs (d)(2)(i) and (d)(6)(i) and (ii) are excepted from § 155.420(a)(4)(iii), § 155.420(a)(4)(i) and (ii) apply other plan category limitations to them. See also the proposals about applicability of plan category limitations to certain special enrollment periods in this section of this preamble.

¹⁵⁵ Section 155.420(a)(4)(i), (a)(4)(iii)(B), and (a)(4)(iii)(C) also provide that alternatively, if the QHP's business rules do not allow the 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).

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QHP is available), as outlined in § 156.140(b). However, these rules include certain flexibilities to permit enrollees to change metal levels through a special enrollment period related to a change in financial assistance for coverage through the Exchange. For example, § 155.420(a)(4)(ii)(A) 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 to ensure that they can access this new benefit.

We propose to add a new flexibility at § 155.420(a)(4)(ii)(C) to allow enrollees and their dependents who become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of a lower metal level. Under this proposal, these special enrollment periods in paragraph (d)(6)(i) and (ii) for becoming newly ineligible for APTC would be addressed in paragraph (a)(4)(ii)(C), and so they will no longer be subject to the separate rules in paragraph (a)(4)(iii). Therefore, we further propose to revise paragraph (a)(4)(iii) to include them in the list of triggering events excepted from the limitations at paragraph (a)(4)(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 with a gold-level QHP who loses eligibility for APTC and sees an increase to his or her monthly premium payment could change to a bronze-level plan, or to catastrophic coverage if they are otherwise eligible.

This proposed change is similar to other recent amendments that we have made to the regulations at § 155.420(a)(4). For example, in response to concerns from HHS Navigators, other enrollment assisters, and agents and brokers based on their experiences with consumers who, upon losing eligibility for CSRs, could not afford cost sharing for their current silver-level QHP,

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In the May 14, 2020 **Federal Register** (85 FR 29204), the 2021 Payment Notice final rule amended paragraph (a)(4)(ii) to permit enrollees and their dependents who are enrolled in a silver-level QHP and who become newly ineligible for CSRs in accordance with paragraph (d)(6)(i) or (ii) to change to a QHP one metal level higher or lower than silver, beginning January 2022.

We are proposing this new flexibility because in recent months, we have also heard concerns from agents and brokers that some consumers who qualify for the special enrollment period in accordance with § 155.420(d)(6)(i) or (ii) because they lose eligibility for APTC based on an income increase may lose a significant amount of financial assistance without having gained enough income to continue to afford the coverage they selected when APTC was available to them. For example, consider a qualified individual who estimates an annual household income of \$49,000 per year and enrolls in a gold plan during open enrollment with a \$1,100 per month (\$13,200 per year) premium and monthly APTC of \$600. This qualified individual could experience an income increase of less than \$2,000, lose APTC based on an income of more than 400 percent FPL, and be required to pay over \$7,000 more annually for their current plan.¹⁵⁶ While this individual would qualify for a special enrollment period due to a loss of eligibility for APTC per paragraph (d)(6)(i), they would not be able to change from a gold plan to a silver or bronze plan (or to a catastrophic plan, if they were eligible) in order to pay a lower monthly premium, because paragraph (a)(4)(iii)(A) provides that these enrollees may only change to another QHP within their current plan's metal level.

¹⁵⁶ 26 CFR 1.36B-2(b)(1) provides that to be eligible for a PTC, the taxpayer's household income must be at least 100 percent but not more than 400 percent of the FPL for the taxpayer's family size for the taxable year. Per the HHS Poverty Guidelines for 2020, 400 percent of the FPL for 2020 for an individual in the contiguous 48 states and DC is \$51,040.

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Enrollees can also lose eligibility for APTC due to a change in household size, without experiencing any change in income. For example, assume a Virginia family of two parents and a 20-year old child, who has no income and is not a full-time student, applies during open enrollment in 2020 and qualifies for APTC based on a projected 2021 household income of \$75,000, an amount less than 400 percent of the FPL for a household of three (\$86,880 in the contiguous 48 states and DC).¹⁵⁷ During 2021 the child becomes employed and by May 2021 has earned enough income so that the parents will not be permitted to claim the child as a tax dependent for 2021. As a result, the family's household size for 2021 will be two instead of three as projected during open enrollment, resulting in the family's \$75,000 household income falling above 400 percent of the FPL for a household of two (\$68,960 in the contiguous 48 states and DC). Because those whose household income exceeds 400 percent of the FPL are ineligible for APTC, the reduction in the parents' household size due to not being permitted to claim their child as a tax dependent results in the parents' loss of APTC eligibility mid-year, and outside the annual open enrollment period.

Loss of APTC based on not being permitted to claim as a tax dependent an individual projected at open enrollment to be a tax dependent (loss of a projected tax dependent) is likely a less common challenge, because loss of a projected tax dependent who was previously enrolled in the same plan as other household members may also result in a lower premium for remaining household members. However, in some cases the decrease in premium may not be enough to make up for the loss of APTC.

¹⁵⁷ These examples use 2020 FPL information to determine APTC eligibility for 2021 because, per 26 CFR 1.36B-1(h), the FPL for computing the PTC for a taxable year is the FPL in effect on the first day of the initial or annual open enrollment period preceding that taxable year. For example, the Assistant Secretary for Planning and Evaluation (ASPE) released 2020 FPL information in January of 2020, and so 2020 FPL information applies during the 2020 open enrollment period for 2021 coverage.

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In many cases, individuals enrolling in Exchange coverage during open enrollment will not anticipate experiencing a situation in the middle of the plan year like those described above. Even if they are aware that they could have a small increase in household income or lose a projected tax dependent, they may not realize that these changes could make them newly ineligible for APTC. Furthermore, sometimes these changes are not foreseeable. Additionally, it is reasonable for individuals who complete an application and then shop for coverage on HealthCare.gov to select a QHP based on premiums that are reduced by the APTC amount for which they are eligible at the time of plan selection, particularly if they do not realize that their financial assistance could change based on loss of a projected tax dependent or a small household income change during the coming year.

In addition to allowing enrollees to change to a plan with a lower premium based on losing a potentially significant amount of financial assistance due to a relatively small change in income or a change in household size, we also note that this proposal is necessary to protect consumers from gaps in coverage due to unaffordability because price differences between QHPs of different metal levels can be significant. For example, in states using the federal enrollment platform, on average silver plan premiums are 34 percent more expensive than bronze plan premiums, and gold plan premiums are 14 percent more expensive than silver plan premiums.¹⁵⁸ Our analysis suggests similar differences in State Exchanges, but we invite comment on whether this is the case and how it impacts current Exchange enrollees.

While this proposal is designed to provide Exchange enrollees who lose APTC with the chance to select lower-cost coverage, we recognize that changing to a new QHP mid-plan year

¹⁵⁸ Calculated based on information in the “Plan Year 2020 Qualified Health Plan Choice and Premiums in HealthCare.gov States” report. Available at: <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2020QHPPremiumsChoiceReport.pdf>.

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may cause enrollees to incur additional out of pocket costs as a new QHP selection typically resets the deductible and other accumulators. We believe that Exchange enrollees who lose APTC eligibility are best able to weigh the trade-off between reset accumulators or maintaining an affordable monthly premium. Enrollees who qualify to make a new plan selection for an applicable special enrollment period already must consider this question. However, we request comment on whether this proposal would increase the risk that consumers will change plans without taking into account potential disadvantages, and on strategies to help mitigate this risk, such as consumer education.

Finally, we acknowledge that enrollees may lose APTC eligibility and qualify for a special enrollment period due to their APTC loss for a reason other than a change in household income or tax family size. For example, a currently-enrolled individual or household could lose APTC and qualify for the related special enrollment period due to an expired inconsistency regarding projected annual household income, or because the Exchange has information that they are eligible for or enrolled in other qualifying coverage that is considered MEC such as most Medicaid coverage, CHIP, or the Basic Health Program (BHP), through the periodic data matching process described in § 155.330(d), and therefore are ineligible for APTC. When consumers lose eligibility for APTC for these reasons, we encourage them to confirm whether the Exchange has correctly terminated their eligibility for APTC. If not, consumers' best option may be to correct the Exchange's records related to the issue that resulted in their APTC loss; for example, they could provide documentary evidence to the Exchange of their projected annual household income that they attested to on their application and upon which their APTC amount was based, or return to their application and attest that they do not have other qualifying coverage such as Medicare, Medicaid/CHIP, or the BHP, if applicable. While HHS performs

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extensive outreach to ensure that consumers understand and can act on these options, some enrollees in this situation may choose to use their special enrollment period due to APTC loss to enroll in a plan of a lower metal level either instead of or in addition to addressing the issue that caused them to lose APTC. We seek comment on whether stakeholders have concerns with this possibility, and on how HHS can help ensure that enrollees who lose eligibility for APTC because of failure to provide information to the Exchange to confirm their APTC eligibility can understand and take action on steps needed to do so, even if they also have the flexibility to change to a plan of a lower metal level. Relatedly, we seek comment on whether Exchanges should limit the flexibility proposed in this rule only to enrollees who qualify for a special enrollment period because they lost APTC eligibility due to a change in household income or tax family size, and continue to apply the current rule at 155.420(a)(4)(iii)(A) to enrollees who qualify for a special enrollment period because they lost APTC for any other reason. We also seek comment on whether such a policy would impose significant additional burdens on Exchanges.

HHS believes that this proposal is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium. However, we request comment on whether there are concerns with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether we should instead only permit an enrollee to change to a plan one metal level lower than their current QHP. We also request comment from issuers on whether there are concerns about impacts such as experiencing a decrease in premium receipt from enrollees who opt to change to

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a lower-cost plan, or whether they view adverse selection as a possibility. We request comment from Exchanges, in particular, on implementation burden associated with this change to current plan category limitations rules, including on whether we should instead, in order to reduce this burden, permit current enrollees and currently enrolled dependents who qualify for this SEP to change to a plan of any metal level – that is, simply exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether. We also request comment from all stakeholders, including those who have or represent individuals with preexisting conditions, on whether such a change would significantly increase risk for adverse selection.

Finally, we also considered whether to propose additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with paragraph (d)(6)(i) or (ii) to change to a QHP of a higher metal level. While we recognize becoming newly eligible for APTC may increase the affordability of higher metal level plans for some individuals, we believe including this flexibility would largely exempt the special enrollment periods at paragraph (d)(6)(i) and (ii) from the rules at 155.420(A)(4)(iii), imposing risks of adverse selection for Exchanges by permitting individuals to change coverage levels in response to health status changes. Furthermore, while we believe the proposed flexibilities for individuals who become newly ineligible for APTC are needed in order to promote continuous coverage for individuals who can no longer afford their original plan choice, no similar affordability and continuous coverage concerns exist for enrolled consumers who gain APTC during the coverage year. Accordingly, at this time we are not proposing additional plan flexibility for enrollees who become newly eligible for APTC. We invite comment on whether we should consider additional flexibilities for this population in the future and the anticipated impact of such a policy.

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We seek comment on these proposals.

b. Special Enrollment Periods – Untimely Notice of Triggering Event

We propose to allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and was otherwise reasonably unaware that a triggering event occurred to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. We also propose to allow such persons to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event. Finally, we propose conforming amendments to § 147.104 (b)(2)(ii) so that these proposals would also apply to off-Exchange individual market health coverage.

In accordance with § 155.410(a)(2), an Exchange may only allow qualified individuals and enrollees to enroll in coverage during the annual open enrollment period as specified in § 155.410(e), and during special enrollment periods as specified in § 155.420. An Exchange must allow a qualified individual or enrollee to enroll in or change from one QHP to another if one of the triggering events described in § 155.420(d) occurs. Furthermore, under § 155.420(c)(1), a qualified individual or enrollee generally has until 60 days after the date of the triggering event to select a QHP. Section 155.420(c)(2) and (3), provide exceptions to this general rule under which a qualified individual or enrollee may enroll prior to the date of a triggering event. Section 155.420(c)(4) provides a final exception under which a qualified individual or enrollee may have less than 60 days to enroll. Coverage effective dates are outlined in § 155.420(b) and vary depending on the SEP triggering event, but in all cases are either on or after the date of the triggering event.

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Because the time period during which a qualified individual may enroll through a special enrollment period is determined by the triggering event, a qualified individual who does not know the triggering event has occurred may not have sufficient time to enroll in coverage. Generally, the triggering events described in § 155.420(d) and related plan selection timelines under § 155.420(c) are premised on the assumption that an individual will become aware of a triggering event in time to make a plan selection within the time allotted under § 155.420(c). For example, the rules anticipate that qualified individuals or enrollees will receive timely notice of the day they will lose employer-sponsored coverage or the day they will gain a dependent such that 60 days is ample time for the individual to apply for enrollment through an applicable special enrollment period and select a plan. However, our experience operating the Federal Exchange has shown that there are circumstances in which an individual reasonably may not be aware of an event that triggers special enrollment period eligibility until after the triggering event has occurred. This proposal would allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event or was otherwise reasonably unaware that a triggering event occurred, to qualify for an applicable special enrollment period and select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. This proposal will also allow the qualified individual, enrollee, or dependent to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event.

For example, an employer fails to pay its share of premium for an insured employer-sponsored health plan and enters a grace period beginning April 1st, which will expire on May 31st. Because the employer intends to satisfy its premium liability before the end of the grace period, the employer does not notify participants and beneficiaries in the plan of the non-

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payment or the risk of termination of its employer-sponsored coverage retroactive to April 1st. The employer is unable to timely satisfy the premium debt, and the issuer of the employer-sponsored health coverage terminates coverage for the participants and beneficiaries retroactively to April 1st. Neither the employer nor the issuer of the employer-sponsored health plan notify the participants and beneficiaries of the beginning of the grace period or that coverage would be terminated as of April 1st. On July 10th, the participants and beneficiaries first receive notice from the issuer that their coverage terminated as of April 1st. In accordance with the circumstances described in 26 CFR 54.9801-6(a)(3)(i), due to the employer's failure to timely pay premiums, the participants and beneficiaries of the employer-sponsored health plan lost eligibility for the coverage and are eligible for the special enrollment period provided in § 155.420(d)(1)(i). Per paragraph (d)(1)(i), the triggering event for special enrollment periods due to loss of MEC is the last day the consumer would have coverage under his or her previous plan or coverage. But in this scenario, affected participants and beneficiaries, through no fault of their own, were not aware of their loss of MEC until more than 60 days following the last day they had coverage. Thus, without the measure we propose here, the participants and beneficiaries in this example would not be able to use the special enrollment period at paragraph (d)(1)(i), because more than 60 days had passed since the relevant triggering event without their having selected a new plan. Some participants and beneficiaries of employer-sponsored health plans experienced similar circumstances during the COVID-19 PHE and sought individual health insurance coverage through the FFEs, exposing a perceived gap in current special enrollment period rules.

Another circumstance in which an individual may not be aware that a triggering event occurred involves technical errors that block an individual from enrolling in coverage through an

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Exchange. Section 155.420(d)(4) specifies that an individual is eligible for a special enrollment period if, among other things, their erroneous non-enrollment in a QHP was due to an error on the part of the Exchange or one of its agents. In this case, the error itself is the triggering event, and the date it occurs serves as the beginning of the special enrollment period. However, as in the case of the loss of employer-sponsored coverage discussed above, an individual may not be aware that an error has occurred. In some cases, the Exchange may not be aware that a technical error has occurred which prevented individuals from enrolling until a subsequent investigation is conducted. This process may take several weeks, during which time an impacted individual may not be aware that they were unable to enroll due to an error and therefore qualify for a special enrollment period. There may even be cases in which an Exchange does not identify the issue and the impacted population and notify them until more than 60 days after the triggering event occurred.

We propose to amend § 155.420 by adding paragraph (c)(5) to specifically provide that if a qualified individual, enrollee, or dependent does not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event occurred, the Exchange must allow them to select a new plan within 60 days of the date that they knew, or reasonably should have known, of the occurrence of the triggering event. Additionally, we propose to add paragraph (b)(5) to clarify that when a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period, the Exchange must allow the such persons the option to choose the earliest coverage effective date for the triggering event under paragraph (b) that would have been available if they had received timely notice of the triggering event. In addition, we propose that the Exchange must also provide the qualified individual, enrollee or

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dependent the option to choose the effective date that would otherwise be available pursuant to the other provisions in paragraph (b).

Lastly, we propose a conforming edit to § 147.104(b)(2) that would incorporate these amendments by reference in the regulations governing special enrollment periods for off-Exchange coverage, so that these proposed special enrollment rules would apply to issuers of non-grandfathered coverage in the individual market, both on- and off-Exchange. We also separately propose a change § 147.104(b)(2)(ii) to clarify how the special enrollment period in § 155.420(d)(4) applies off-Exchange. This change is discussed in further detail in the preamble to part 147.

We seek comment on these proposals.

c. Cessation of Employer Contributions to COBRA as Special Enrollment Period Trigger

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA)¹⁵⁹ (Pub. L. 99-272, April 7, 1986) provides for a temporary continuation of group health coverage following, among other circumstances, employees' separation from an employer, for reasons other than gross misconduct, in instances where such separation would otherwise cause termination of coverage. Although employees who elect to receive COBRA continuation coverage may be required by their former employer to pay their former employer's share of the premiums as well as their own,¹⁶⁰ such employers will sometimes pay all or a portion of their former employee's premium for part or all of the COBRA coverage period.

¹⁵⁹ <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf>.

¹⁶⁰ Individuals electing COBRA may also be required by their former employer to pay a 2 percent administrative fee. See <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf>.

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In accordance with the policy currently in place on the Exchanges using the Federal platform, we propose to amend § 155.420(d)(1) to state that the complete cessation of employer contributions for COBRA continuation coverage serves as a triggering event for special enrollment period eligibility.¹⁶¹ The triggering event would occur as of the last day of the period for which COBRA continuation coverage was paid for, in whole or in part, by the employer. Exchange regulations at paragraph (d)(1)(i) provide that when a qualified individual or his or her dependent loses MEC as defined by § 155.20 they gain eligibility for a special enrollment period, during which they can enroll in a QHP. Paragraph (e) states that loss of MEC as described in paragraph (d)(1) includes the circumstances listed at 26 CFR 54.9801-6(a)(3)(i) through (iii). These provisions describe conditions under which someone may qualify for a special enrollment period for group health plan coverage, including paragraphs (a)(3)(i), “Loss of eligibility for coverage,” and (a)(3)(iii), “exhaustion of COBRA continuation coverage.”

In implementing special enrollment periods for Exchanges using the Federal platform, HHS has provided a loss of MEC special enrollment period under § 155.420(d)(1)(i) for individuals whose COBRA costs change because their former employer completely ceases contributions and as a result they must pay the full cost of premiums. However, loss of coverage based on complete cessation of employer contributions for COBRA coverage might not have been treated as a triggering event by issuers of individual coverage off-Exchange or by State Exchanges. HHS believes it is important that individuals have access to a special enrollment period in the individual market when their former employer completely ceases contributions to

¹⁶¹ Because employers are not required to charge a 2 percent administrative fee to individuals who elect COBRA, we do not include this fee in the definition of “employer contributions.” For purposes of this section, if an individual enrolled in COBRA continuation coverage without employer contributions (so that the individual was responsible for 100 percent of the premiums) but was not required to pay a 2 percent administrative fee, this would not be considered an employer contribution for the purposes of the proposed special enrollment period.

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COBRA continuation coverage, because the cost of COBRA continuation coverage premiums are substantial, rendering this type of coverage unaffordable for many people to whom it would be available.¹⁶² Ensuring that this special enrollment period is widely available would help promote continuity of coverage for those who could not maintain their COBRA continuation coverage without employer subsidies. HHS therefore seeks to make this special enrollment period available throughout the individual market.

Therefore, we propose to amend § 155.420 by adding paragraph (d)(1)(v) stating that a special enrollment period is triggered when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, and the employer completely ceases its contributions. Similar to the special enrollment period for termination of employer contributions to employer-sponsored coverage at 26 CFR 54.9801-6(a)(3)(ii), the triggering event would occur as of the last day of the period for which COBRA continuation coverage is paid for, in part or in full, by an employer. We also propose to make conforming changes to the preceding paragraphs to reflect the addition of this new paragraph. Furthermore, since complete cessation of employer contributions toward employer-sponsored continuation coverage under state mini-COBRA laws¹⁶³ serves as a special enrollment period triggering event under 26 CFR 54.9801-6(a)(3)(ii), which is incorporated by § 155.420(e), we propose to include in paragraph (v) a reference to this regulation for purposes of clarity. These changes would make explicit HHS's current policy with regard to the Exchanges using the Federal platform, and would ensure that individual market policies sold off-Exchange and through State Exchanges align with it. In addition, amending paragraph (d)(1) to explicitly

¹⁶² <https://www.kff.org/private-insurance/issue-brief/key-issues-related-to-cobra-subsidies/>.

¹⁶³ <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf>.

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include complete cessation of employer contributions to COBRA continuation coverage as a special enrollment period triggering event would mitigate confusion among employers and employees, as well as other stakeholders, about their options regarding COBRA continuation coverage and special enrollment period eligibility.

As with other special enrollment periods described in § 155.420(d)(1), in the Exchanges, this special enrollment period would be subject to the provisions in paragraph (a)(4)(iii)(B) and (C), which allow dependents and non-dependent qualified individuals who qualify for a special enrollment period to be added to the QHP of a household member who is already enrolled in Exchange coverage, or to enroll separately in a plan of any metal level. We also propose that the Exchange must provide the qualified individual, enrollee, or dependent the effective date that would otherwise be available pursuant to the other provisions at paragraph (b)(2)(iv). In accordance with paragraph (c)(2), an individual eligible for this special enrollment period would have 60 days before or after the triggering event (in this case, the last day for which the qualified individual or dependent has COBRA continuation coverage to which an employer is contributing) to select a QHP. We propose that this special enrollment period, which would be incorporated by reference in the guaranteed availability regulations at § 147.104(b)(2), apply with respect to individual health insurance coverage offered through and outside of an Exchange.

To help clarify the circumstances that would trigger the proposed special enrollment period, we include the following examples:

Example 1: An individual is laid off from a job in June, and enrolls in COBRA continuation coverage for which the employer pays 100 percent of the premiums (the employer does not require payment of a 2 percent administrative fee). On September 3rd of that year, the employer informs the individual that it is completely terminating contributions to the individual's

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COBRA continuation coverage as of September 30th, and beginning on October 1st, the individual will be responsible for 100 percent of the COBRA continuation coverage premiums. As a result, the individual decides to end COBRA coverage on October 1st. Because September 30th is the last day for which the individual had COBRA continuation coverage for which the employer was contributing, the individual has 60 days before and after this date (in this case, between August 1st and November 29th) to select an individual market plan through a special enrollment period.

Example 2: Same scenario as in the first example, except that the employer was paying only 25 percent of the COBRA continuation coverage premiums before the employer completely terminated contributions. The individual decides to maintain COBRA continuation coverage despite the loss of employer contributions. Even though the individual retained COBRA continuation coverage, the individual is still eligible to select a QHP through a special enrollment period from August 1st to November 29th, 60 days before or after the last day on which the individual had COBRA continuation coverage with employer contributions.

In addition to this proposal, HHS is also considering addressing situations in which an employer reduces, but does not completely cease, its contributions for COBRA continuation coverage. In particular, we are considering adding to proposed paragraph § 155.420(d)(1)(v) a provision that a reduction of employer contributions for COBRA continuation coverage would also serve as a special enrollment period trigger. The triggering event would occur the last day on which an individual has COBRA continuation coverage that was subsidized at the higher amount. Reduction of employer contributions to COBRA continuation coverage has not previously been treated as a triggering event for purposes of the loss of MEC special enrollment period under paragraph (d)(1)(i). However, HHS believes it is important to address this scenario

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as a way of promoting continuity of coverage for those who would not be able to maintain their COBRA continuation coverage with a reduced employer contribution. A similar special enrollment period for reduction of employer contributions to employer-sponsored coverage is not currently provided for under the provisions at 26 CFR 54.9801-6(a)(3)(i) through (iii). However, HHS believes it is important to provide a special enrollment period for reductions in employer contributions toward COBRA coverage because there are differences between employer-sponsored coverage and COBRA, such as the fact that COBRA continuation coverage is not subject to an affordability test under 26 CFR 1.36B-2(c)(3)(v) for purposes of determining potential eligibility for APTC and/or CSR, and the fact that individuals must generally pay more for COBRA continuation coverage than for employer-sponsored coverage.

Because this situation is not addressed in regulation or by HHS policy, we seek comment on whether stakeholders believe it would be helpful to codify such a special enrollment period if an employer reduces, but does not completely cease, its contributions to COBRA continuation coverage. In addition, we seek comment on whether HHS should also adopt a threshold for the level of reduction of employer contributions for COBRA continuation coverage that should trigger a special enrollment period.

We seek comment on this proposal.

d. Special Enrollment Period Verification

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all FFEs and SBE-FPs and encouraged states to do the same in State Exchanges. Special enrollment period verification has addressed concerns that allowing individuals to enroll in coverage through a special enrollment period without electronic or document-based verification could

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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.¹⁶⁴

Since 2017, Exchanges using the federal platform have implemented pre-enrollment special enrollment period verification for special enrollment period types commonly used by consumers to enroll in coverage. Consumers who are not already enrolled through the Exchange and who apply for coverage through a special enrollment period type that requires pre-enrollment verification by the Exchange must have their eligibility electronically verified using available data sources, or they must submit supporting documentation to verify their eligibility for the special enrollment period before their enrollment can become effective. As stated in the HHS Marketplace Stabilization Rule, special enrollment period verification is only conducted for new enrollees due to the potential for additional burden on issuers and confusion for consumers if required for existing enrollees.

In implementing pre-enrollment verifications for special enrollment periods in the Market Stabilization Rule, HHS did not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications, in order to allow State Exchanges with flexibility to adopt policies that fit the needs of their state.¹⁶⁵ Currently, all State Exchanges now conduct either pre- or post-enrollment verification of at least one special enrollment type, and most State Exchanges have implemented a process to verify the vast majority of special enrollment periods requested by consumers.

¹⁶⁴ 82 FR at 18356.

¹⁶⁵ 82 FR at 18356.

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Therefore, we propose to amend § 155.420 to add paragraph (f) to require all Exchanges to conduct eligibility verification for special enrollment periods. Specifically, we propose to require that Exchanges conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods for consumers not already enrolled in coverage through the applicable Exchange. We are proposing that Exchanges must verify at least 75 percent of new enrollments through special enrollment periods based on the current implementation of special enrollment period verification by Exchanges. If the Exchange is unable to verify the consumer's eligibility for enrollment through the special enrollment period, then the consumer is not eligible for enrollment through the Exchange, and enrollment through the Exchange may be terminated in accordance with 45 CFR 155.430(b)(2)(i). If an Exchange opts to pend a plan selection prior to enrollment, and the Exchange cannot verify eligibility for the special enrollment period, then the consumer will be found ineligible for the special enrollment period, and the plan selection will not result in an enrollment. The determination of how many enrollments would constitute 75 percent would be required to be based on special enrollment period enrollment. This would provide Exchanges with implementation flexibility so they can continue to decide which special enrollment types to verify and the best way to conduct that verification. Exchanges will not be required to verify eligibility for all special enrollment periods, since the cost to verify eligibility for special enrollment period triggering events with very low volumes could be greater than the benefit of verifying eligibility for them.

We also continue the flexibility that State Exchanges currently have to design eligibility verification processes that are appropriate for their market and Exchange consumers, such that State Exchanges may have such flexibility in their approaches for meeting the requirement proposed at § 155.420(f) to verify eligibility for a special enrollment period. Specifically, under

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§ 155.315(h), State Exchanges have the flexibility to propose alternative methods for conducting required verifications to determine eligibility for enrollment in a QHP under subpart D, such that the alternative methods proposed reduce the administrative costs and burdens on individuals while maintaining accuracy and minimizing delay. We propose to use the existing authority at § 155.315(h) to allow State Exchanges to request HHS approval for use of alternative processes for verifying eligibility for special enrollment periods as part of determining eligibility for special enrollment periods under § 155.305(b). This would allow, for instance, the smaller State Exchanges that have administrative burden and cost concerns the option to coordinate with HHS to devise and agree upon the best approach for special enrollment period verification for their specific population. We recognize that State Exchanges may vary in their approach and technical capabilities relating to verification of special enrollment periods and may need additional time to implement this requirement. Therefore, we are proposing to allow Exchanges until plan year 2024 to implement special enrollment period verification.

We seek comment on these proposals. With respect to Special Enrollment Period Verification, we seek comment from States about the 75 percent verification threshold and whether it should be based on past year or current year special enrollment period enrollments, understanding that unforeseen events may occur that may drive up or down enrollments from year-to-year.

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

HHS calculates the required contribution percentage for each benefit year using the most recent projections and estimates of premium growth and income growth over the period from 2013 to the preceding calendar year. Accordingly, we propose the required contribution

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percentage for the 2022 benefit year, calculated using income and premium growth data for the 2013 and 2021 calendar years.

Under section 5000A of the Code, an individual must have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under § 155.605(d)(2), an individual is exempt from the requirement to have MEC if the amount that he or she would be required to pay for MEC (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her projected household income for a year. Although the Tax Cuts and Jobs Act reduced the individual shared responsibility payment to \$0 for months beginning after December 31, 2018, the required contribution percentage is still used to determine whether individuals above the age of 30 qualify for an affordability exemption that would enable them to enroll in catastrophic coverage under § 155.305(h).

The initial 2014 required contribution percentage under section 5000A of the Code was 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 26 CFR 1.5000A-3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. The excess of the rate of premium growth over the rate of income growth is also used for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code.

As discussed elsewhere in this rule, we are proposing as the measure for premium growth the 2022 premium adjustment percentage of 1.4409174688 (or an increase of about 44.1 percent over the period from 2013 to 2021). This reflects an increase of about 6.4 percent over the 2021 premium adjustment percentage ($1.4409174688 \div 1.3542376277$).

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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 (\$61,156 for 2021) exceeds per capita PI for 2013 (\$44,948), carried out to ten significant digits. The ratio of per capita PI for 2021 over the per capita PI for 2013 is estimated to be 1.3605944647 (that is, per capita income growth of about 36.1 percent).¹⁶⁶ This rate of income growth between 2013 and 2021 reflects an increase of approximately 3.9 percent over the rate of income growth for 2013 to 2020 (1.3605944647 ÷ 1.3094029651) that was used in the 2021 Payment Notice. Per capita PI includes government transfers, which refers to benefits individuals receive from federal, state, and local governments (for example, Social Security, Medicare, unemployment insurance, workers' compensation, etc.).¹⁶⁷

Thus, using the 2022 premium adjustment percentage proposed in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2021 would be 1.4409174688 ÷ 1.3605944647, or 1.0590352278. This would result in a proposed required contribution percentage for 2021 of 8.00 × 1.0590352278 or 8.47 percent, when rounded to the

¹⁶⁶ The 2013 and 2021 per capita personal income figures used for this calculation reflect the latest NHEA data, published on March 24, 2020. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS Website, which can be accessed by clicking the "NHE Projections 2019-2028 – 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>.

¹⁶⁷ 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.

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nearest one-hundredth of one percent, an increase of 0.20 percentage points from 2020 (8.47228-8.27392).

Finally, beginning with the 2023 benefit year, we are proposing to publish the required contribution percentage, along with the premium adjustment percentage and the annual cost-sharing limitation parameters, in guidance separate from the annual notice of benefit and payment parameters. For a discussion of the provisions of this proposal, please see the preamble for Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130).

We seek comment on these proposals.

10. Excluding the Special Enrollment Period Trigger in § 155.420(d)(1)(v) from Applying to SHOP Plans (§ 155.726)

Special enrollment periods due to cessation of employer contributions to COBRA continuation coverage are generally not available in the group insurance market. Therefore, in order to maintain consistency between SHOP and the rest of the group insurance market, we propose to amend § 155.726(c)(2)(i) to exclude the special enrollment period trigger in proposed paragraph § 155.420(d)(1)(v) from applying to SHOP plans. For a discussion of the provisions of this proposal, please see the preamble for § 155.420.

We seek comment on this proposal.

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

1. User Fee Rates for the 2022 Benefit Year (§ 156.50)

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a. FFE and SBE-FP User Fee Rates for the 2022 Benefit Year (§ 156.50(c))

Section 1311(d)(5)(A) of the PPACA requires states to ensure that Exchanges are self-sustaining, which may include the state allowing an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specify that a participating issuer offering a plan through an FFE or SBE-FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE-FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE-FP. In addition, OMB Circular No. A-25 establishes federal policy regarding the assessment of user charges under other statutes and applies to the extent permitted by law. Furthermore, OMB Circular A-25 specifically provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from federal activities beyond those received by the general public. Activities performed by the federal government that do not provide issuers participating in an FFE with a special benefit are not covered by this user fee. As in benefit years 2014 through 2021, issuers seeking to participate in an FFE in the 2022 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 2022 benefit year, issuers participating in an FFE will receive special benefits from the following federal activities:

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- 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 propose a 2022 user fee rate for all participating FFE issuers at 2.25 percent of total monthly premiums. This proposed user fee rate reflects our estimates for the 2022 benefit year of costs for operating the Federal Exchanges, premiums, enrollment, and transitions in Exchange models (from the FFE and SBE-FP models to either the SBE-FP, FFE-DE or State Exchange models (state transitions)). The proposed FFE user fee rates are lower than the 3.0 percent FFE user fee rate that we established for benefit years 2020 and 2021, and the 3.5 percent FFE user fee rate that we established for benefit years 2014 through 2019. After accounting for the impact of the lower user fee rate, we estimate that we would have sufficient funding available to fully fund user-fee eligible Exchange activities. We seek comment on this proposed 2022 FFE user fee rate.

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As previously discussed, OMB Circular No. A-25 establishes federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. SBE-FPs enter into a federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and federal programs. Accordingly, in § 156.50(c)(2), we specify that an issuer offering a plan through an SBE-FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, unless the SBE-FP and HHS agree on an alternative mechanism to collect the funds from the SBE-FP or state.

The benefits provided to SBE-FP issuers by the federal government include use of the Federal Exchange information technology platform and call center infrastructure used to support 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. Based on this methodology, we propose to charge issuers offering QHPs through an SBE-FP a user fee rate of 1.75 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE-FP. This proposed rate is lower than the 2.5 percent user fee rate that we had established for benefit year 2021. The lower proposed user fee rate for SBE-FP issuers for the 2022 benefit year reflects our estimates of costs for operating the Federal Exchanges, premiums, enrollment, as well as state Exchange

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transitions for the 2022 benefit year, and the costs associated with performing these services that benefit SBE-FP issuers. We seek comment on the proposed 2022 SBE-FP user fee rate.

b. FFE-DE and SBE-FP-DE User Fee Rates for the 2023 Benefit Year (§ 156.50(c)(3))

Elsewhere in this proposed rule, we propose to allow states served by an FFE or SBE-FP to implement the proposed direct enrollment option under § 155.221(j) beginning with plan year 2023, under which one or more private direct enrollment entities approved by the FFE would operate websites through which consumers may apply for and enroll in a QHP, with or without APTC or CSR (if otherwise eligible). Under the proposed FFE-DE or SBE-FP options, QHP issuers offering plans through the Exchange would receive some of the benefits of the Federal Exchange, however, some consumer outreach, education, and support activities would be provided by the state or through the Federal Exchange.¹⁶⁸

As previously discussed, OMB Circular No. A-25 establishes federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. As such, we propose in new § 156.50(c)(3) to charge issuers offering QHPs through an FFE-DE or an SBE-FP-DE a user fee for the services and benefits provided to those issuers by HHS as the administrator of the Federal Exchange. We propose to charge issuers offering QHPs through an FFE-DE or SBE-FP-DE a user fee rate calculated based on the proportion of FFE user fee eligible costs incurred by HHS that are associated with implementation and operation of the FFE-DE or SBE-FP-DE. We assume that the use of Federal Exchange services will be less for FFE-DE and SBE-FP-DE states in 2023 and beyond than for FFE and SBE-FP states during the same time period. Therefore, to provide some certainty for states that consider a transition to a

¹⁶⁸ See above for more information on the proposed direct enrollment option under § 155.221(j).

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proposed FFE-DE or SBE-FP-DE, we propose a 2023 user fee rate of 1.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an FFE-DE or SBE-FP-DE in plan year 2023. Under the DE option, the Exchange would no longer be providing many of the consumer facing enrollment-related activities that are currently being performed through the Federal platform, or such activities would be substantially reduced. For example, the use of the Marketplace call center and HealthCare.gov website will be substantially diminished. Because of the role of the state in operating SBE-FPs, the value to issuers and the associated costs of operating these functions in FFEs is typically higher. The reduction of these functions and costs therefore is reflected by a larger proposed reduction in the user fee rate for issuers in FFE-DEs from the rate applicable in FFEs (from 2.25 percent to 1.5 percent) than the reduction in the user fee rate for issuers in SBE-FP-DEs from the rate applicable in SBE-FPs (from 1.75 percent to 1.5 percent), resulting in the same proposed user fee rate for these new Exchange options. We seek comment on the FFE-DE or SBE-FP-DE user fee rate, including whether the rate should be state-specific or higher or lower depending on whether the Exchange is a FFE-DE or SBE-FP-DE and the specific services HHS will provide, as outlined in the Federal agreement required under new proposed § 155.221(j)(2)(ii). We will continue to examine costs, enrollment, premium, and state transition estimates for the issuers offering QHPs on the Exchanges using the Federal platform for the 2022 benefit year as we finalize the FFE and SBE-FP user fee rates (including the proposed rates for the new proposed FFE-DE and SBE-FP-DE options for the 2023 benefit year). We seek comment on these proposals.

c. State User Fee Collection Administration (§ 156.50(c)(2))

We also propose to eliminate the state user fee collection flexibility that HHS had previously offered to states in the 2017 Payment Notice. We propose that HHS would not collect

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an additional user fee, if a state so requests, from issuers at a rate specified by the state to cover costs incurred by the state for the functions the state retains. HHS previously provided this flexibility to states in order to help reduce the administrative burden on states of collecting additional user fees. However, our subsequent internal analysis demonstrated that the process of collecting the state portion of the user fee and remitting it to the state, would increase the operational burden and cost incurred by HHS. Therefore, we are amending § 156.50(c)(2) to remove this alternate user fee collection mechanism. We note that this proposal does not change the ability of an SBE-FP to request that HHS collect from the SBE-FP state regulatory entity the total amount that would result from the percent of monthly premiums charged for enrollment through the federal platform, instead of HHS collecting the fee directly from SBE-FP issuers.

d. Eligibility for User Fee Adjustments for Issuers Participating through SBE-FPs
(§ 156.50(d))

We are proposing to amend § 156.50(d) to clarify that issuers participating through SBE-FPs are eligible to receive adjustments to their federal user fee amounts that reflect the value of contraceptive claims they have reimbursed to third-party administrators (TPAs) that have provided contraceptive coverage on behalf of an eligible employer. In the final rules “Coverage of Certain Preventative Services Under the Affordable Care Act,”¹⁶⁹ these relationships were established as a method of both providing contraceptives for women and accommodating the religious beliefs of employers. In the 2017 Payment Notice,¹⁷⁰ we allowed State Exchanges to enter into agreements to rely on the Federal platform for certain Exchange functions to enhance efficiency and coordination between the state and federal programs, and to leverage the systems

¹⁶⁹ 78 FR 39870 (July 2, 2013); 80 FR 41318 (July 14, 2015).

¹⁷⁰ 81 FR 12203 at 12293 (March 8, 2016).

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established by the FFEs to perform certain Exchange functions. Although we recognized that issuers participating in these types of Exchanges were subject to a federal user fee, § 156.50(d) was not amended to reflect the SBE-FP Exchange model. As such, in this rule, we propose to amend § 156.50(d) to explicitly include the issuers offering QHPs through SBE-FPs. We also propose to make conforming changes throughout the regulation text at § 156.50(d) to reflect the user fees applicable to FFEs and SBEs that adopt the DE option, as further discussed elsewhere in this rulemaking.

We seek comment on these proposals.

e. Request for Comments on Alternatives to Exchange User Fees (§ 156.50)

In the 2021 Payment Notice proposed rule we solicited comment on whether to lower the user fee rates in the final rule and any information that might inform future changes to the user fee rate. One commenter questioned the basis of the user fee, stating that the Exchanges do not provide a special benefit to issuers. The commenter asserted that there is no competitive advantage to being on the Exchanges, the existence of the Exchanges are mandated by law, and the benefits associated with user fees all flow to consumers, and not the issuers who pay them.

While the 2021 Payment Notice comment solicitation focused on the rate of the user fee, we appreciate the commenter's concerns regarding the justification for the user fee. Even when government policies seem well established—HHS is in its seventh year applying the Exchange user fee to issuers—it is always helpful to periodically step back and reassess whether a particular policy is still an effective and proper approach, and whether there are better alternatives.

We recognize the Exchanges serve a public purpose defined by the PPACA to facilitate the purchase of QHPs, determine eligibility for insurance affordability programs, and assist in

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enforcing the individual and employer shared responsibility provisions. The Exchanges also provide special benefits to issuers, including regulatory services and sales services similar to the services provided by agents and brokers. Whether or not the current balance of funding sources is appropriate based on the portion of activities that support a public purpose compared to a special benefit to issuers presents an important question.

In addition, we recognize the application of the Exchange user fee raises important fairness questions regarding who ultimately pays the fee and how much they pay. Issuers directly pass Exchange user fees on to their enrollees in the form of higher premiums, which issuers specifically document in their rate filings to justify their rates. Therefore, the people who effectively pay the Exchange user fee are largely limited to (1) people who pay the full premium without the benefit of PTCs subsidies and (2) federal taxpayers who tend to fully fund the marginal increase in premiums due to the user fee for people who receive PTC subsidies. The fact that single risk pool regulations under 45 CFR 156.80(d)(1)(ii) require the index rate to be adjusted on a market-wide basis based on Exchange user fees means that enrollees who purchase coverage outside the Exchange from a QHP issuer must pay higher premiums to support the Exchange. In addition, we recognize average premiums vary substantially across states and rating regions—varying from a statewide average of \$389 to \$942 in 2019¹⁷¹—which is largely due to variations in claims experience. As a result, the per enrollee user fee can vary substantially based on factors that are not related to the cost of operating the Exchanges.

Because the Exchange user fee is specifically included in premium as a component of the index rate under 45 CFR 156.80(d)(1)(ii), we also recognize the fee raises important fairness

¹⁷¹ “Early 2020 Effectuated Enrollment Snapshot,” July 23, 2020. Available at <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Early-2020-2019-Effectuated-Enrollment-Report.pdf>.

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questions regarding the treatment of commissions for agents and brokers in the MLR calculation. As noted previously, the Exchange provides sales services similar to the services provided by agents and brokers. Yet the cost of these services are treated completely differently within the MLR calculation. Exchange sales services are considered part of the premium, which helps the issuer meet the MLR requirement. Conversely, agent and broker commissions are treated as administrative costs, which counts against the issuer meeting the MLR requirement. As a result, the user fee combined with the method for calculating the MLR may give the Exchange a competitive advantage over agents and brokers.

Recognizing these concerns with the Exchange user fee, we are considering and seek comment on both the appropriateness of an alternative revenue source and the type of an alternate revenue source to ensure Exchanges can cover the costs of the Exchange in an effective, appropriate, and fair manner. While these comments would not change the funding source of Exchange related functions in this rule, the comments submitted in response to this solicitation may be used for further proposals.

2. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or after January 1, 2020 (§ 156.111)
 - a. Annual Reporting of State-Required Benefits

In the 2021 Payment Notice, we amended § 156.111(d) and added paragraph (f) to require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual and/or small group market that are considered to be “in addition to EHB” in accordance with § 155.170(a)(3).

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At § 156.111(f), we also required states to 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. Under this requirement, a state's submission must describe all benefits requirements under state mandates applicable to QHPs in the individual or small group market that were imposed on or before December 31, 2011, and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as all benefits requirements under state mandates that were imposed any time after December 31, 2011, applicable to the individual or small group market. The state's report is also required to describe whether any of the state benefit requirements in the report were amended or repealed after December 31, 2011. Information in the state's report is required to be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

We also finalized § 156.111(d)(2) to specify that if the state does not notify HHS of its required benefits considered to be in addition to EHB by the annual reporting submission deadline, or does not do so in the form and manner specified by HHS, HHS will identify which benefits are in addition to EHB for the state for the applicable plan year. HHS's identification of which benefits are in addition to EHB will become part of the definition of EHB for the applicable state for the applicable plan year.

In the 2021 Payment Notice, we finalized that the annual reporting of state-required benefits would begin in plan year 2021 and set a July 1, 2021 deadline for states to submit to HHS their first complete reporting package. We now propose July 1, 2022 as the deadline for states to submit to HHS the complete reporting package for the second year of reporting. This would mean that states would notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB that QHPs are required to cover in plan year 2022 or after plan

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year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline). As part of this reporting, states must also identify which state-required benefits are not in addition to EHB and do not require defrayal in accordance with § 155.170, and provide the basis for the state's determination, by the July 1, 2022 reporting submission deadline.

The first reporting cycle was intended to set the baseline list of state-required benefits applicable to QHPs in the individual and/or small group market. For each subsequent annual reporting cycle thereafter, the state is only required to update the content in its report to add any new benefit requirements and to indicate whether benefit requirements previously reported to HHS have been amended or repealed. If a state has not imposed, amended, or repealed any state benefit requirements since the prior year's reporting deadline, the state is still required to report to HHS that there have been no changes to state-required benefits since the previous reporting cycle. In such a scenario, the state should submit the same reporting package as the previous reporting cycle and affirmatively indicate to HHS that there have been no changes.

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.

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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 6, 2022, as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year. 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 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 flexibility through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that the deadline applicable to state selection of a new benchmark plan would also apply to this state opt-in process. Therefore, we also propose May 6, 2022, as the deadline for states to notify HHS 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.

3. Premium Adjustment Percentage (§ 156.130)(e))

We propose the 2022 benefit year annual premium adjustment percentage using the most recent estimates and projections of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) from the NHEA, which are calculated by CMS'

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Office of the Actuary. For the 2022 benefit year, the premium adjustment percentage will represent the percentage by which this measure for 2021 exceeds that for 2013.

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 three other 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 final rule¹⁷² and 2015 Market Standards Rule¹⁷³ 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. The 2020 Payment Notice final rule¹⁷⁴ established that we will calculate the average per capita premium as private health insurance premiums minus premiums paid for Medicare supplement (Medigap) insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees. Additionally, as finalized in the 2021 Payment Notice final rule,¹⁷⁵ we will finalize the premium adjustment percentage and related

¹⁷² 79 FR 13743.

¹⁷³ 79 FR 30240.

¹⁷⁴ 84 FR 17454.

¹⁷⁵ See 85 FR 29228.

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parameters for the 2022 benefit year using the NHEA data available at the time of this proposed rule for the 2022 benefit year.

As such, we propose that the premium adjustment percentage for 2022 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 2021 (\$7,036) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 (\$4,883).¹⁷⁶ Using this formula, the proposed premium adjustment percentage for the 2022 benefit year is 1.4409174688 (\$7,036/\$4,883), which represents an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 44.1 percent over the period from 2013 to 2021.

Based on the proposed 2022 premium adjustment percentage, we propose the following cost-sharing parameters for benefit year 2022.

a. Maximum Annual Limitation on Cost Sharing for Plan Year 2022

We propose to increase the maximum annual limitation on cost sharing for the 2022 benefit year based on the proposed value calculated for the premium adjustment percentage for the 2022 benefit year. As finalized in the EHB final rule¹⁷⁷ at § 156.130(a)(2), for the 2022 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium

¹⁷⁶ The 2013 and 2021 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 2019-2028 – 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>.

¹⁷⁷ See 78 FR 12847 through 12848.

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adjustment percentage for 2022. 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 1.4409174688 for 2022 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, 2013,¹⁷⁸ we propose that the 2022 benefit year maximum annual limitation on cost sharing would be \$9,100 for self-only coverage and \$18,200 for other than self-only coverage. This represents an approximately 6.4 percent increase above the 2021 parameters of \$8,550 for self-only coverage and \$17,100 for other than self-only coverage. We seek comment on these proposals.

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

We propose for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking, to use the reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations determined by the methodology we established beginning with the 2014 benefit year, as further described later in this section of the preamble.

Sections 1402(a) through (c) of the 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

¹⁷⁸ See Revenue Procedure 2013-25, 2013-21 IRB 1110. <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

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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 2022 maximum annual limitation on cost sharing would be \$9,100 for self-only coverage and \$18,200 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2022 plan year and our proposed results.

Consistent with our analysis for the 2014 through 2021 benefit years' reduced maximum annual limitation on cost sharing, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to the proposed estimated 2022 maximum annual limitation on cost sharing for self-only coverage (\$9,100). The test plan designs are based on data collected for 2021 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2022, the test silver level QHPs included a PPO with typical cost-sharing structure (\$9,100 annual limitation on cost sharing, \$2,775 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing (\$7,400 annual

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limitation on cost sharing, \$3,050 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$9,100 annual limitation on cost sharing, \$4,800 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: \$500 inpatient stay per day, \$500 emergency department visit, \$30 primary care office visit, and \$55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into a draft version of the 2022 benefit year AV Calculator¹⁷⁹ and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. As with prior years, we found that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 100 and 150 percent of FPL (2/3 reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (2/3 reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively).

However, as with prior years, we continue to find that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL (1/2 reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. Furthermore, as with prior years, 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 would cause an increase in AV that exceeds the maximum 70 percent level in the statute.

¹⁷⁹ Available at <https://www.cms.gov/ccio/resources/regulations-and-guidance/index>.

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Beginning with the 2023 benefit year, we are proposing to publish the required contribution percentage, along with the premium adjustment percentage and the annual cost-sharing limitation parameters, in guidance. For additional discussion of the provisions of this proposal, please see the preamble for Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130).

The calculation of the reduced maximum annual limitation on cost sharing has remained consistent since the 2014 Payment Notice due to year-over-year consistency of the results of our analysis regarding the effects of the reduced maximum annual limitation on cost sharing on the AV of silver plan variations. Therefore, as a result of the apparent stability of those results, and consistent with prior Payment Notices, we propose to continue to use the maximum annual limitation on cost sharing reductions of 2/3 for enrollees with a household income between 100 and 200 percent of FPL, 1/5 for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond. We would continue to review the effects of these reductions annually, and should we determine that this approach should be changed to better reflect the statutorily specified AVs for silver plan variations, we would propose to change these reductions through notice and comment rulemaking.

Specifically, we propose to continue to use the methodology described above for analyzing the effects of the reduced maximum annual limitation on cost sharing on the AV of silver plan variations to verify that the reductions do not result in unacceptably high AVs before we publish these values in guidance for a given benefit year. Subsequently, if a future analysis using this methodology supports a modification to the reduced maximum annual limitation for

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any of the household income bands for a future benefit year, we would propose those modifications to the reduced maximum annual limitations through notice-and-comment rulemaking, as appropriate.

We 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 result in the AV of the QHP meeting the specified level.

We seek comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing calculation methodology for the 2022 benefit year and beyond. We also seek comment on the proposed reduced annual limitations on cost sharing for the 2022 benefit year (Table 9).

We note that for 2022, as described in § 156.135(d), states are permitted to request HHS's approval for state-specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1, 2020 deadline.

TABLE 9: Reductions in Maximum Annual Limitation on Cost Sharing for 2022

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)	\$3,000	\$6,000
Individuals eligible for CSRs under § 155.305(g)(2)(ii) (151-200 percent of FPL)	\$3,000	\$6,000
Individuals eligible for CSRs under § 155.305(g)(2)(iii) (201-250 percent of FPL)	\$7,250	\$14,500

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c. Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130)

Since the 2014 benefit year, HHS has published the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage parameters through notice-and-comment rulemaking. Beginning with the 2023 benefit year, we propose to publish these parameters in guidance by January of the year preceding the applicable benefit year, unless HHS is changing the methodology for calculating the parameters, in which case, we would do so through notice-and-comment rulemaking. We additionally propose to publish in guidance the premium adjustment percentage and related parameters using the most recent NHEA income and premium data that is available at the time these values are published in guidance or, if HHS is changing the methodology for calculating these parameters, at the time these values are proposed in notice-and-comment rulemaking. Publication of these parameters prior to the release of updates to the NHEA data, which typically (but not always) occurs in February or March, is consistent with the 2021 Payment Notice policy to finalize the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage using NHEA data that would be available at the time that the proposed rule would have been published.

In the EHB final rule,¹⁸⁰ HHS established at § 156.130(e) that HHS will publish the annual premium adjustment percentage in the annual HHS notice of benefit and payment

¹⁸⁰ 78 FR 12834 through 12833.

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parameters. Additionally, in the 2014 Payment Notice final rule,¹⁸¹ HHS established at § 156.420(a)(1)(i), (2)(i), and (3)(i), that the reduced annual limitations on cost sharing would be published in the applicable benefit year's annual HHS notice of benefit and payment parameters. Due to the timing of publication of the annual HHS notice of benefit and payment parameters final rule in past years, stakeholders have suggested that when HHS is not changing the calculation methodology for these parameters, HHS should publish earlier the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage. These stakeholders assert that an earlier publication would allow issuers to incorporate these parameters for rate setting and the submission of QHP benefit templates earlier than would be possible if the parameters were published in the applicable benefit year's notice of benefit and payment parameters.

In addition, because the methodologies used to calculate the premium adjustment percentage, required contribution percentage, and maximum annual limitation on cost sharing have been previously established through rulemaking, the calculation of these amounts is a function of entering the applicable figures into the established equations, and therefore, does not require rulemaking to establish. Additionally, the calculation of the reduced maximum annual limitation on cost sharing has remained consistent since the 2014 Payment Notice final rule. Therefore, as discussed earlier in this proposed rule, we have proposed the reductions to the maximum annual limitation on cost sharing as well as the methodology for determining whether these reductions raise plan AVs above acceptable levels for the 2022 benefit year and beyond.

With these methodologies in place, beginning with the 2023 benefit year, we propose to amend §§ 156.130(e) and 156.420(a) to reflect that we would publish the premium adjustment

¹⁸¹ 78 FR 15409.

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percentage, along with the maximum annual limitation on cost sharing, the reduced maximum annual limitation on cost sharing, and the required contribution percentage in guidance by January of the year preceding the applicable benefit year (for example, the 2023 premium adjustment percentage would be published in guidance no later than January 2022), unless HHS is amending the methodology to calculate these parameters, in which case HHS would amend the methodology and publish the parameters through notice-and-comment rulemaking.

We believe that publishing the final premium adjustment percentage and associated final parameters in guidance annually instead of through notice-and-comment rulemaking is consistent with our efforts to provide information to stakeholders in a timely manner.

We seek comment on these proposals.

4. Network Adequacy Standards (§ 156.230)

45 CFR 156.230, which implements section 1311(c)(1)(B) of the PPACA, describes the network adequacy standards for QHP issuers that use a provider network. We have received questions regarding whether the requirements at § 156.230 apply to a plan that does not use a provider network, such as an indemnity plan, and does not vary benefits based on whether enrollees receive services from an in-network or out-of-network provider.

Nothing in the PPACA requires a QHP issuer to use a provider network. Accordingly, a QHP issuer may choose to design a QHP that does not use a provider network, and to provide equal benefits for covered services without regard to whether the issuer has a network participation agreement with the provider that furnishes the covered services. Section 156.230 does not impose any network adequacy certification requirement for QHPs that do not use a provider network, and has not since the inception of the Exchanges. To address any ambiguity in this section, we propose to codify this longstanding interpretation at paragraph (f) to provide that

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a plan that does not vary benefits based on whether the issuer has a network participation agreement with the provider that furnishes the covered services would not comply with the network adequacy standards at paragraphs (a) through (e) in order to be certified as a QHP. This proposal would simply clarify existing QHP requirements and would not change or add any additional QHP certification requirement.

We invite comment on this proposal.

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

In the 2021 Payment Notice, CMS finalized a requirement that under § 156.270(b)(1), QHP issuers must send termination notices with effective dates and reason for the termination to enrollees for all termination events. We finalized this as proposed, noting that all commenters who weighed in on this topic supported our proposal. This policy became effective July 13, 2020. We are not proposing any changes to paragraph (b)(1) beyond what we finalized in the 2021 Payment Notice for the reasons discussed below.

In finalizing this rule, CMS inadvertently omitted discussion of two comments opposing the proposal. These comments raised concerns about unnecessary additional administrative costs and IT builds, and noted that a termination notice could be confusing in certain scenarios—for example, if the enrollee switches between QHPs offered by the same issuer, a termination notice from their issuer could cause confusion. These commenters proposed instead that Exchanges should be required to clearly convey the eligibility termination reason and effective date in the Exchange's own eligibility notices, consistent with the data conveyed to issuers on 834 termination transactions.

We are sensitive to commenters' concerns that issuers need sufficient time to build IT systems to implement this policy. In response, CMS issued guidance allowing issuers using the

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federal platform enforcement discretion until February 1, 2021 to implement the new termination notice requirement.¹⁸²

However, the comments in opposition of the proposal do not change CMS's policy goals underlying our decision to finalize the rule as proposed. FFEs do not send termination notices for any termination scenario other than citizenship data-matching issue expirations and terminations associated with Medicare PDM when the enrollee has elected at plan selection to terminate Exchange coverage when found dually enrolled. The FFEs also do not send termination notices in enrollee-initiated terminations which must be requested at the Exchange. Similarly, the FFEs do not send termination notices when an enrollee switches QHPs within the same issuer. This is all appropriate, because the issuer is the primary communicator to the enrollee about their coverage. We still believe that termination notices would be helpful in these scenarios, even in plan selection changes, because an enrollee switching QHPs could have their premium, cost sharing, and provider network affected. As one of the comments in support of our proposal noted, it is important for the enrollee to have in writing the actual termination date for their records, in case of miscommunication with the issuers about the preferred date or to later dispute an inaccurate Form 1095-A. Another commenter agreed that issuers should send termination notices during voluntary terminations associated with Medicare PDM as it would help the enrollee confidently transition to Medicare.

Complaints about terminations are one of the largest sources of casework. More consistent communication is part of the solution. We believe consumers should be notified of these changes, even if they initiated them so that enrollees have a record that the issuer

¹⁸² "Enforcement Safe Harbor for Qualified Health Plan Termination Notices During the 2019 Benefit Year," August 26, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Termination-Notices-Enforcement-Discretion.pdf>.

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completed the request. Issuers are the proper messenger of termination noticing for many reasons. For example, Exchange issuers historically are the senders of termination notices, and some issuers acknowledge in their comments that they already do send termination notices in all scenarios. Furthermore, the issuer has record of the termination date needed for the termination notice before the Exchange in some cases, such as some retroactive termination requests handled through casework, and State Exchange issuer terminations described in § 155.430(d)(iv). Indeed, one reason we proposed regulating in this area is that we were receiving detailed questions from issuers about which termination scenarios required issuer notices; we believe requiring issuer termination notices for all scenarios in the long run makes the requirement simpler.

Therefore, we are not proposing any changes to § 156.270(b)(1) beyond what we finalized in the 2021 Payment Notice.

6. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295)

Section 6005 of the PPACA added section 1150A(a)(2) of the Act to require a PBM under a contract with a Medicare Part D plan sponsor or Medicare Advantage plan that offers a Medicare Part D plan, or with a QHP offered through an Exchange established by a state under section 1311 of the PPACA¹⁸³ to provide certain prescription drug information to the Secretary, at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer or their PBM must report.¹⁸⁴ Section

¹⁸³ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the PPACA. *King v. Burwell*, 576 U.S. 988 (2015).

¹⁸⁴ This information is: the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract; the aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance

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1150A(c) of the Act requires the information reported to be kept confidential and not to be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.¹⁸⁵

In the 2012 Exchange Final Rule, we codified the requirements contained in section 1150A of the Act with regard to QHPs at § 156.295. In that rule, we interpreted section 1150A of the Act to require QHP issuers to report the information described in section 1150A(b) of the Act and did not specify the responsibilities of PBMs that contract with QHP issuers to report this information. On January 28, 2020¹⁸⁶ and on September 11, 2020,¹⁸⁷ we published notices in the **Federal Register** and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act to HHS.¹⁸⁸

a. QHP Issuer Responsibilities

Elsewhere in this rule, we propose to add new part 184 to address the responsibilities of PBMs under the PPACA and to add § 184.50 to codify in regulation the statutory requirement that PBMs that are under contract with an issuer of one or more QHPs report the data required by section 1150A of the Act. Accordingly, we propose to revise § 156.295(a) to state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs,

programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and, the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

¹⁸⁵ The purposes are: as the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the PPACA.

¹⁸⁶ 85 FR 4993 through 4994.

¹⁸⁷ 85 FR 56227 through 56229.

¹⁸⁸ Pharmacy Benefit Manager Transparency. CMS-10725. Available at <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995pra-listing/cms-10725>.

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the QHP issuer will report the data required by section 1150A of the Act to HHS. We propose corresponding revisions throughout § 156.295 to remove the applicability of the reporting requirement for PBMs under this section and propose revising the title to “Prescription drug distribution and cost reporting by QHP issuers”.

As explained in the preamble at § 184.50, we acknowledge that section 1150A places responsibility on both the QHP issuer and their PBMs to report this prescription drug data. Generally, where a QHP issuer contracts with a PBM, the PBM is more likely to be the source of the data that must be reported. Therefore, to reduce overall burden, rather than requiring the QHP issuer to serve as a conduit between its PBM and HHS, or unnecessarily requiring both the PBM and the QHP issuer to submit duplicated data, we propose to implement section 1150A to make QHP issuers responsible for reporting this data directly to the Secretary only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Where a QHP contracts with a PBM, the PBM is responsible for reporting data to the Secretary as required by § 184.50.

Although we are unaware of any QHP issuer that does not currently utilize a PBM, we believe that, together, the proposals to revise § 156.295 and to add § 184.50 would ensure the collection of data required by section 1150A of the Act in all circumstances, including when a QHP issuer does not use a PBM to administer its prescription drug benefit. Retaining the requirement for QHP issuers to report data at § 156.295 when they do not contract with a PBM would ensure that the data is consistently collected every plan year.

We also propose to remove § 156.295(a)(3) to remove the requirement for QHP issuers to report spread pricing amounts when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Spread pricing amounts are only present where a

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PBM acts as an intermediary between the QHP issuer and a drug manufacturer. If a QHP issuer does not contract with a PBM, no such intermediary exists and it is not possible for QHP issuers to report this data.

We seek comment on these proposals.

b. Reporting of Data by Pharmacy Type

Section 1150A(b)(1) of the Act requires the Secretary to collect certain QHP prescription drug data¹⁸⁹ by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). This requirement was previously codified at § 156.295(a)(1). In the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule, we recognized that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files.¹⁹⁰ We understand that these types continue not to be standard classifications currently captured in industry databases or files, as indicated by comments submitted in response to the January 28, 2020 notice in the **Federal Register** soliciting public comment on the collection of information requirements of this collection.¹⁹¹ To reduce the burden of this collection, we propose to revise § 156.295(a)(1) to remove the requirement to report the data described at section 1150A(b)(1) of the Act by pharmacy type. We intend to collect this information at a time when this requirement would impose reasonable burden. We seek comment on ways that we may

¹⁸⁹ Section 1150A(b)(1) requires the reporting of the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed.

¹⁹⁰ See 77 FR 22072 at 22093.

¹⁹¹ See 85 FR 4993 through 4994.

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collect the data by pharmacy type without creating unreasonable burden and any existing definitions that may exist that could be leveraged for this purpose. We also seek comment on the time and costs required for PBMs to begin reporting by pharmacy type, if definitions were finalized.

7. Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, and User Fee Programs (§ 156.480)

a. Application of Requirements to Issuers in State Exchanges and SBE-FPs

In the second Program Integrity Rule, we finalized general provisions related to the oversight of QHP issuers in relation to APTC and CSRs.¹⁹² We explained that since APTC and CSR payments are federal funds which pass from HHS directly to QHP issuers, it is necessary for HHS to oversee QHP issuer compliance in these areas, regardless of whether the QHP is offered through a State Exchange or an FFE. As such, to effectively oversee the payment of APTC and CSRs by QHP issuers, HHS established standards in part 156, subpart E for QHP issuers participating in FFEs and State Exchanges. We also noted that in states with State Exchanges, the state would have primary enforcement authority over QHP issuers participating in the state's individual market exchange that were not in compliance with the standards set forth in part 156, subpart E.¹⁹³ However, if the State Exchange does not enforce such standards, HHS would enforce compliance with these requirements, including the imposition of CMPs on QHP issuers participating in State Exchanges using the same standards and processes for QHP issuers participating in FFEs set forth in part 156, subpart I.¹⁹⁴ In the second Program Integrity Rule, we also finalized general provisions that require issuers offering QHPs in an FFE maintain all

¹⁹² See 78 FR 65077 and 65078.

¹⁹³ See the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR at 65077 and 65078.

¹⁹⁴ Ibid.

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documents and records and other evidence of accounting procedures and practices, which are critical for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs.¹⁹⁵ As finalized in 45 CFR 156.705(a)(1), this includes the authority for HHS to include periodic auditing of the QHP issuer's financial records related to the participation in an FFE. To date, we have leveraged this authority to conduct user fee audits of QHP issuers participating in an FFE.

In this rulemaking, we propose amendments to consolidate HHS audit authority regarding APTC, CSR, and user fee audits by expanding the audit authority under § 156.480(c) to also capture user fees audits by HHS, or its designee, of QHP issuers participating in an FFE. Additionally, as part of determining whether APTC and CSR amounts were properly paid to issuers, and whether user fee amounts were properly collected, HHS regularly identifies discrepancies in issuer records caused by issuer non-compliance with other applicable Exchange operational standards. Examples include failure to correctly effectuate or terminate coverage, or to correctly calculate premiums. In addition, we propose to apply the same framework to QHP issuers participating in SBE-FP states. As such, QHP issuers in SBE-FP states would be required to comply with HHS audits under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees.

We further propose that in situations where the state fails to substantially enforce such standards, HHS would enforce compliance, including imposing CMPs using the same standards set forth in part 156, subpart I. Based on our experience conducting audits of APTC, CSRs, and user fees, we also propose several amendments to § 156.480(c) to ensure we can effectively

¹⁹⁵ See 78 FR 65078 and 65079.

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oversee the payment of these amounts by QHP issuers, regardless of Exchange type (for example, FFE, State Exchange, or SBE-FP).

As detailed below, to further support our program integrity efforts in these areas, we propose to amend § 156.480(c) to codify additional details regarding HHS audits and to capture authority for HHS to conduct compliance reviews of QHP issuer compliance with the applicable Federal APTC, CSR, and user fee standards,¹⁹⁶ including the consequences for the failure to comply with an audit. In addition, we propose amendments to §§ 156.800 and 156.805 to set forth the framework for HHS enforcement of the applicable Federal APTC, CSR, and user fee standards in situations where state authorities fail to substantially enforce those standards with respect to the QHP issuers participating in State Exchanges and SBE-FPs.

We seek comment on these proposals, including with respect to how HHS could coordinate with State Exchanges, SBE-FPs, and state authorities to address non-compliance by QHP issuers with applicable Federal APTC, CSRs, and user fee standards. We seek comment on ways to balance enforcement by State Exchanges and SBE-FPs and the protection and oversight of federal funds by HHS.

b. Audits and Compliance Reviews of APTC, CSRs, and User Fees (§ 156.480(c))

In prior rulemaking, we codified authority for HHS to audit an issuer that offers a QHP in the individual market through an Exchange to assess compliance with the requirements of part 156, subpart E.¹⁹⁷ We also previously codified general authority for HHS to periodically audit a QHP issuer's financial records related to its participation in an FFE.¹⁹⁸ Recently, HHS

¹⁹⁶ The applicable Federal standards for APTC and CSRs are found in part 156, subpart E, which apply to QHP issuers participating in all Exchanges types (FFEs, State Exchanges and SBE-FPs). The applicable Federal standards for user fees are found in 45 CFR 156.50, which apply to QHP issuers in FFEs and SBE-FPs.

¹⁹⁷ 78 FR 65077 and 65078.

¹⁹⁸ See 45 CFR 156.705(a)(1). Also see 78 FR 65078 and 65079.

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completed the audits for the 2014 benefit year CSR payments. During these audits, HHS encountered challenges working with some issuers. Specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion and receiving data in a format that is readily usable for purposes of conducting the audit. As such, similar to the proposals related to audits of issuers of reinsurance-eligible plans and risk adjustment covered plans discussed earlier in this proposed rule, we propose to amend § 156.480(c) to provide more clarity around the issuer requirements for APTC and CSR audits. The proposed amendments codify more details about the audit process and clarify issuer obligations with respect to these audits, including what it means to comply with an audit and the consequences for failing to comply with such requirements. Additionally, we propose to amend § 156.480(c) to also capture and clarify HHS's ability to audit FFE and SBE-FP user fees. As such we proposed to rename § 156.480, "Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, and User Fee Programs." HHS currently reviews compliance with applicable Federal user fee standards when conducting APTC audits because the same data is used for both purposes; as such, there will be minimal increased burden as a result from this codification.

We also propose several amendments to § 156.480(c) to expand the oversight tools available to HHS beyond traditional audits to also provide authority for HHS to conduct compliance reviews of QHP issuers to assess compliance with the applicable Federal APTC, CSR, and user fee standards. These proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would be conducted to confirm QHP issuer compliance with the APTC, CSR, and user fee standards in subpart E of part 156 and 45 CFR 156.50 for user fees, as applicable, and they would generally extend to QHP issuers

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participating in all Exchanges.¹⁹⁹ A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.²⁰⁰ For example, HHS may require an issuer to submit data pertaining to specific data submissions. We believe this flexibility is necessary and appropriate to provide HHS a mechanism to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. We intend to continue our collaborative oversight approach and coordinate with State Exchanges and SBE-FPs to ensure QHP issuer compliance with the applicable standards in part 156, subpart E and 45 CFR 156.50.

First, we propose to rename § 156.480(c) to “Audits and Compliance Reviews” in order to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate QHP issuer compliance with the applicable Federal APTC, CSR, and user fee standards. We similarly propose to update the introductory language in § 156.480(c) to incorporate a reference to HHS compliance reviews. As amended, § 156.480(c) would provide that HHS or its designee may audit and perform compliance reviews to assess whether an issuer that offers a QHP in the individual market through an Exchange is in compliance with the applicable requirements of subpart E, part 156, and 45 CFR 156.50. We propose to capture in a new sentence in the amended § 156.480(c) that HHS would conduct these compliance reviews consistent with the standards set forth in 45 CFR 156.715. As detailed earlier in this preamble, these oversight tools would be available to HHS to evaluate compliance by QHP issuers participating in all Exchanges with the applicable Federal APTC, CSR, and user fee standards.

¹⁹⁹ HHS does not intend to conduct user fee compliance reviews of QHP issuers participating in State Exchanges that do not rely on the Federal platform. Such reviews would be limited to QHP issuers participating in FFE and SBE-FP states.

²⁰⁰ See 78 FR 65100.

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Second, we propose to add new § 156.480(c)(1) to establish notice and conference requirements for these audits. Proposed new paragraph (c)(1) states that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an QHP issuer under § 156.480(c). Under proposed paragraph (c)(1)(i), HHS proposes to codify that all audits would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Third, HHS proposes to add new paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (c)(2)(i), we propose to require the issuer to ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section. In new proposed paragraph (c)(2)(ii), we propose to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (c)(1)(i). For example, for CSR audits, HHS may request that QHP issuers provide a re-adjudicated claims data extract for the selected sample of policies to verify accuracy of the re-adjudication process and reported amounts (this would include verification of all elements necessary to perform accurate re-adjudication) and data extract containing incurred claims for the selected sample of policies to verify accuracy of actual amount the enrollee(s) paid for EHBs via an Electronic File Transfer. As another example, for APTC audits, issuers may be asked to provide data to validate and support APTC payments received for the applicable benefit year.

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Fourth, under proposed § 156.480(c)(2)(iii), HHS proposes to require that issuers respond to any audit notices, letters, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We believe that the proposed requirements in paragraph (c)(2) are necessary and appropriate to ensure the timely completion of audits and to protect the integrity of the APTC, CSR, and user fee programs and the payments made thereunder.

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

Sixth, under § 156.480(c)(3), HHS proposes that it would share its preliminary audit findings with the issuer, and further proposes that the issuer would then have 30 calendar days to respond to such findings in the format and manner as specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary audit findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal

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information via Electronic File Transfer. HHS proposes under paragraph (c)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. In new proposed paragraph (c)(3)(ii), if the issuer timely responds and disputes the preliminary audit findings within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

Seventh, HHS proposes to add a new section at § 156.480(c)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We note that the actions set forth in the final audit report could require an issuer to return APTC or CSRs or make additional user fee payments. HHS further proposes that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

If an issuer fails to comply with the audit requirements set forth in new proposed § 156.480(c), HHS proposes in paragraph (c)(5)(i) that HHS would notify the issuer of payments received that the issuer has not adequately substantiated, and in new proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated if the APTC, CSR, or user fee debt is not paid. Therefore, the continued failure to respond to or cooperate with an audit under paragraph (c) and provide the necessary

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information to substantiate the payments made could result in HHS recouping up to 100 percent of the APTC or CSR payments made to an issuer for the benefit year(s) that are the subject of the audit if the APTC, CSR, or user fee debt is not paid.

APTC and CSR amounts recovered by HHS as a result of an audit under § 156.480(c) would be paid to the U.S. Treasury. User fee amounts recovered by HHS as a result of an audit under paragraph (c) would be paid to the ACA Marketplace user fee program collection account.

Lastly, HHS proposes to add a new paragraph (c)(6) to § 156.480 to codify HHS' ability to enforce the applicable Federal APTC, CSR, and user fee standards if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements. In instances where HHS enforces compliance with the applicable APTC, CSR, and user fee standards with respect to QHP issuers participating in State Exchanges or SBE-FPs, HHS would use the same standards and processes as outlined in §§ 156.805 and 156.806 for QHP issuers participating in an FFE with respect to the imposition of CMPs. This would include the proposed extension of the process outlined in § 156.901, *et seq.* for the QHP issuer to appeal the imposition of CMPs. For a discussion of the framework and proposed accompanying penalties for non-compliance in situations where HHS is responsible for enforcement of these requirements, see the below discussion of proposed changes to §§ 156.800 and § 156.805.

We seek comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes and processes for issuers to respond to audit notices and requests for information and for issuers to request extensions of those timeframes, and the proposals related to HHS's authority to enforce compliance with the above requirements if a State Exchange or SBE-FP is not enforcing or fails to substantially enforce one or more of these requirements.

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8. Subpart I—Enforcement Remedies in Federally-Facilitated Exchanges; Available remedies; Scope. (§ 156.800)

In this proposed rule, we propose to rename Subpart I to “Enforcement Remedies in the Exchanges,” and to make other amendments to clarify that HHS has the ability to impose CMPs when it is enforcing the applicable federal requirements in part 156, subpart E and 45 CFR 156.50 for user fees, regardless of whether the Exchange is established and operated by a state (including a regional Exchange or subsidiary exchange) or by HHS.²⁰¹ As explained in prior rulemaking, in states where there is a State Exchange or SBE-FP, the State Exchange or SBE-FP has primary enforcement authority over QHP issuers participating in the Exchange and ensuring compliance with the applicable Federal APTC, CSR, and user fee standards.²⁰² However, consistent with the framework established in section 1321(c)(2) of the PPACA, HHS has authority to step in to enforce requirements related to the operation of Exchanges and the offering of QHPs through Exchanges if a state fails to do so.^{203,204} As such, in the case of a determination by the Secretary that a State Exchange or SBE-FP has failed to enforce or substantially enforce a federal requirement (or requirements) related to QHP issuer participation in the individual market Exchange, HHS has authority to step in and enforce QHP issuer compliance with the requirement(s).

Through its cross-reference to section 2723(b) of PHS Act, section 1321(c)(2) of the PPACA authorizes the Secretary to impose CMPs for non-compliance with applicable federal

²⁰¹ Exchange models include State Exchanges, SBE-FPs, and FFEs. HHS does not intend to use this authority to impose CMPs related to user fee standards applicable to QHP issuer participating in State Exchanges.

²⁰² See the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR 65077 and 65078.

²⁰³ Ibid.

²⁰⁴ Section 1321(c)(2) of the PPACA provides that the enforcement framework established in section 2736(b), which was renumbered 2723(b), of the PHS Act shall apply to the enforcement of requirements established in section 1321(a)(1).

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Exchange requirements. In this proposed rule, we propose to codify HHS authority to impose CMPs for non-compliance by QHP issuers that participate or have participated in a State Exchange or SBE-FP in situations where HHS steps in to enforce certain requirements. Specifically, this proposal is focused on ensuring compliance with the standards for APTC, CSR payments, and user fees captured in part 156, subpart E and 45 CFR 156.50. Under this proposal, we would apply the bases and follow the processes for imposing CMPs as set forth in § 156.805, would send a notice of non-compliance as set forth in § 156.806, and would extend the administrative review and appeal process set forth in § 156.901, *et seq.* to provide a forum for QHP issuers in State Exchanges and SBE-FPs to appeal the imposition of CMPs by HHS. We are not proposing to extend the authority to decertify a QHP under § 156.800(a)(2) for non-compliance by QHP issuers in State Exchanges or SBE-FPs; QHP de-certification in State Exchanges or SBE-FPs would remain an available enforcement tool for the applicable Exchange. This proposal is not intended to duplicate state enforcement efforts, as HHS generally depends on State Exchanges and SBE-FPs to enforce federal requirements applicable to QHPs and QHP issuers participating in the state's individual market Exchange. The proposed amendments are instead intended to establish an enforcement framework to capture situations where HHS is responsible for enforcement if a State Exchange or SBE-FP fails to do so and is focused on the Federal APTC, CSR, and user fee requirements in order to protect federal funds.

We expect that states that established a State Exchange or SBE-FP will enforce all applicable federal requirements applicable to QHPs and QHP issuers participating in Exchanges, including the applicable APTC, CSR, and user fee standards captured in part 156, subpart E and 45 CFR 156.50. However, to address situations where a State Exchange or SBE-FP fails to enforce these federal Exchange requirements, consistent with the framework established in

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section 2723(b) of the PHS Act, we propose that if HHS determines that a State Exchange or SBE-FP lacks authority or has otherwise failed to substantially enforce the requirements captured in part 156, subpart E or 45 CFR 156.50, HHS would step in to enforce these requirements with respect to QHP issuers participating in the State Exchange or SBE-FP. Once this determination is made, HHS would become responsible for enforcement and would take appropriate action to ensure QHP issuer compliance with the applicable requirement(s),²⁰⁵ and may impose CMPs, if appropriate. To more clearly capture HHS's authority to impose CMPs in these situations, we proposed to amend the introductory sentence to § 156.800(a) to replace the current references to the "Federally-facilitated Exchange" with references to "an Exchange." We also propose to amend § 156.800(b) to remove the word "only" from the sentence describing the scope of HHS sanctions with respect to QHP issuers participating in FFEs and to add a new second sentence that affirms HHS authority to impose CMPs for non-compliance with the applicable requirements in part 156, subpart E and 45 CFR 156.50 by QHP issuers participating in State Exchanges and SBE-FPs.

We intend to continue our collaborative enforcement approach and would coordinate our actions with state efforts to avoid duplication and to streamline oversight of the administration of APTC, CSRs, and user fees. We solicit comments for how HHS can collaborate with State Exchanges, SBE-FPs, and state authorities to proactively address non-compliance with applicable federal requirements and share compliance tools regarding CSRs, APTC and user fees.

²⁰⁵ As detailed earlier, when HHS is responsible for enforcement of these Exchange requirements, we also propose to extend authority for HHS to pursue a compliance review under §§ 156.480(c) and 156.715 to evaluate compliance with federal APTC, CSR, and user fee requirements by a QHP issuer participating in a State Exchange or SBE-FP.

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9. Bases and Process for Imposing Civil Money Penalties in Federally-facilitated Exchanges (§ 156.805)

We also propose to amend § 156.805 to more clearly reflect HHS's authority to impose CMPs due to non-compliance with respect to the applicable Federal APTC, CSR, and user fee standards against a QHP issuer participating in a State Exchange or SBE-FP. Under this proposal, we would use the same bases and process currently captured in § 156.805 for imposing CMPs on QHP issuers participating in an FFE. More specifically, in § 156.805, we propose renaming this section to "Bases and process for imposing CMPs in the Exchanges," and also propose to amend the introductory language in § 156.805(a) to use the words "an Exchange," instead of "Federally-facilitated Exchange," to more clearly capture HHS's authority to impose CMPs on QHP issuers participating in State Exchanges and SBE-FPs who fail to comply with the applicable requirements in part 156, subpart E or § 156.50 in situations where HHS is responsible for enforcement. We similarly propose to modify § 156.805(a)(5)(i) where the reference to "HHS" currently appears to also incorporate a reference to "an Exchange" to clarify that all QHP issuers must avoid intentionally or recklessly misrepresenting or falsifying APTC, CSR, and user fee information to both HHS and Exchanges, regardless of whether HHS or a state operates the Exchange. We propose this amendment to clarify that HHS has authority to impose CMPs against QHP issuers participating in State Exchanges and SBE-FPs who misrepresent or falsify APTC, CSR, and user fee information provided to HHS in situations where HHS is responsible for enforcement of the requirements in part 156, subpart E or § 156.50, including when HHS is performing an audit or compliance review under § 156.480(c). If HHS seeks to use this authority to impose CMPs against a QHP issuer participating in a State Exchange or SBE-

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FP, we propose the issuer would have the opportunity to appeal the CMPs following the existing framework for administrative hearings in § 156.901, *et seq.*

Finally, we propose to add a new paragraph (f) to § 156.805 to capture in this regulation details on the circumstances requiring HHS enforcement of the applicable requirements in part 156, subpart E and § 156.50. Consistent with the framework established in section 2723 of the PHS Act and section 1321(c) of the PPACA, we propose in new § 156.805(f)(1) that HHS's authority to enforce in these situations would be limited to situations where the State Exchange or SBE-FP notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, *et seq.* that a State Exchange or SBE-FP is failing to substantially enforce these requirements.²⁰⁶ In new proposed § 156.805(f)(2), we affirm that when HHS is responsible for enforcement in these circumstances, HHS may impose CMPs on an issuer in the State Exchange or SBE-FP, in accordance with the bases and process set forth in this section. As noted above, this includes the ability for a QHP issuer in a State Exchange or SBE-FP to appeal the imposition of CMPs by HHS following the existing framework for administrative hearings in § 156.901, *et seq.*

We propose that HHS would apply the same process HHS uses to determine when a state is failing to substantially enforce PHS Act requirements in determining whether a State Exchange or SBE-FP is substantially enforcing the applicable Federal APTC, CSR, and user fee standards. More specifically, we propose that if an audit of a QHP issuer in a State Exchange or SBE-FP demonstrates the State Exchange or SBE-FP's failure to enforce the applicable Federal APTC, CSR, and user fee standards, HHS would investigate the State Exchange or SBE-FP's enforcement and follow the process set forth in 45 CFR 150.207 if necessary. We propose that if

²⁰⁶ See, for example, 45 CFR 150.203.

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HHS receives or obtains information (including information discovered through an audit) that a State Exchange or SBE-FP may not be enforcing the applicable requirements in part 156, subpart E, or § 156.50, HHS may initiate the process described in 45 CFR 150.207 to determine whether the State Exchange or SBE-FP is failing to substantially enforce these requirements. Mirroring the process set forth in 45 CFR 150.207 for making determinations regarding substantial enforcement of PHS Act requirements, HHS would follow the procedures in §§ 150.209 through 150.219 to determine if a State Exchange or SBE-FP is failing to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50. If HHS believes there is a reasonable question whether there has been a failure to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50, HHS would send a notice, as described in 45 CFR 150.213, identifying the applicable requirement(s) that allegedly have not been substantially enforced to the proper State Exchange or SBE-FP officials using the process outlined in 45 CFR 150.211. We propose that, following the process described in 45 CFR 150.215, HHS may extend, for good cause, the time the State Exchange or SBE-FP has for responding to the notice, such as if there is an agreement between HHS and the State Exchange or SBE-FP that there should be a public hearing on the State Exchange or SBE-FP's enforcement, or evidence that the State Exchange or SBE-FP is undertaking expedited enforcement activities. Using the process described in 45 CFR 150.217, if at the end of the extension period HHS determines that the State Exchange or SBE-FP has not established to HHS's satisfaction that it is enforcing the applicable requirement(s), we propose that HHS would consult with the appropriate State Exchange or SBE-FP officials, notify the State Exchange or SBE-FP of its preliminary determination that the State Exchange or SBE-FP has failed to substantially enforce the requirement(s) and that the failure is continuing, and permit the State

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Exchange or SBE-FP a reasonable opportunity to show evidence of substantial enforcement. If, after providing notice and a reasonable opportunity for the State Exchange or SBE-FP to show that it has corrected any failure to substantially enforce, HHS finds that the failure to substantially enforce has not been corrected, HHS would notify the State Exchange or SBE-FP of its final determination using the process described in 45 CFR 150.219. Therefore, we propose that after a determination that a State Exchange or SBE-FP is not or cannot substantially enforce the applicable requirements in part 156, subpart E or § 156.50, HHS could impose CMPs on issuers in the State Exchange or SBE-FP if there is cause for such imposition. HHS would also provide a notice of non-compliance, consistent with § 156.806, to QHP issuers in State Exchanges or SBE-FPs prior to imposing CMPs.

We seek to work collaboratively with State Exchanges, SBE-FPs, and state authorities for any topics of mutual concern and oversight activities where possible. We also seek comment to this proposal and ways in which HHS and state authorities can efficiently and effectively enforce federal standards related to APTC, CSRs, and user fees.

We also propose that if the changes made to the above § 156.800 and to § 156.805 are finalized as proposed, we would also apply § 156.903 such that an administrative law judge's authority also extends to CMPs imposed against QHP issuers in State Exchanges and SBE-FPs under § 156.805. Specifically, we propose to amend § 156.903(a) to extend the authority to State Exchanges and SBE-FPs so that the ALJ has the authority, including all the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a CMP on a QHP offered in a FFE, State Exchange, or SBE-FP.

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10. Subpart J – Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947)

We propose to change the title to subpart J, removing the reference to “in Federally-Facilitated Exchanges” to make clear it applies to QHPs participating in any Exchange type to align with accompanying proposed changes outlined above to §§ 156.800 and 156.805. We also propose several procedural changes to provisions in subpart J of part 156 related to administrative hearings consistent with the amendments discussed in the preamble to part 150. These proposed changes are intended to align with the Departmental Appeals Board’s current practices for administrative hearings to appeal CMPs. Specifically, we propose changes that would remove requirements to file submissions in triplicate and instead require electronic filing. This change is reflected in the proposed amendments to the definition of “Filing date” in § 156.901, to the introductory text in § 156.927(a), and to the service of submission requirements captured in paragraph (b). We also propose to allow for the option of video conferencing as a form of administrative hearing by amending the definition of “Hearing” in § 156.901 and to the requirements outlined in § 156.919(a) related to the forms for the hearing, § 156.941(e) related to prehearing conferences, and § 156.947(a) related to the record of the hearing. Finally, we propose to update § 156.947 to allow the ALJ to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date. We seek comment on these proposals.

11. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

Section 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 quality and price. Section 1311(c)(4)

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of the PPACA directs the Secretary to establish an enrollee satisfaction survey that will assess enrollee satisfaction with each QHP offered through the Exchanges with more than 500 enrollees in the prior year.

Based on this authority, HHS finalized rules in May 2014 to establish standards and requirements related to QHP issuer data collection and public reporting of quality rating information in every Exchange.²⁰⁷ To balance HHS's strategic goals of empowering consumers through data, minimizing cost and burden on QHP issuers, and supporting state flexibility, HHS developed a phased-in approach to establishing quality standards for Exchanges and QHP issuers, collecting and reporting quality measure data, and displaying quality rating information across the Exchanges. Since 2015, we have collected clinical quality measure data and enrollee experience survey measure data and generated quality ratings to provide reliable, meaningful information about QHP quality performance data across Exchanges. In addition, since 2016, select states²⁰⁸ with FFEs and State Exchanges have displayed QHP quality rating information as a tool for consumer decision-making while shopping for health insurance coverage in an Exchange. Beginning with the open enrollment period for plan year 2020, CMS displayed the QHP quality rating information for all Exchanges that used the HealthCare.gov platform, including the FFEs and SBE-FPs. State Exchanges that operated their own eligibility and enrollment platform were similarly required to display QHP quality ratings beginning with the

²⁰⁷ See 79 FR 30240 at 30352. Also see 45 CFR 155.1400, 155.1405, 156.1120 and 156.1125.

²⁰⁸ Prior to the PY2020 nationwide display of quality rating information, states that displayed QHP quality rating information included California, Colorado, Connecticut, Maryland, Michigan, Montana, New Hampshire, New York, Rhode Island, Virginia, Washington, and Wisconsin.

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open enrollment period for plan year 2020, but had some flexibility to customize the display of the QHP quality rating information.²⁰⁹

Through valuable feedback from the QRS and QHP Enrollee Survey Call Letter process and continued engagement with health plan issuer organizations, healthcare quality measurement experts, state representatives, consumer advocates and other stakeholders, we continue to learn about populations buying insurance coverage across the Exchanges and about areas of improvement for these programs. We also continue to assess potential refinements to the QRS rating methodology and the QHP Enrollee Survey to prioritize strategies to improve value for consumers and to reduce the burden of quality reporting.

As part of the 2020 QRS and QHP Enrollee Survey Call Letter process, we received many comments requesting that we remove levels of the QRS hierarchy to help streamline and improve consumer understanding of the quality rating information. While we are not proposing amendments to the QRS or to the QHP Enrollee Survey as part of this rulemaking, we seek comment on the removal of one or more levels of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We previously described the general overall framework for the QRS, including details on the hierarchical structure of the measure set and the elements of the QRS rating methodology.²¹⁰ Currently, the QRS measures are organized into composites, domains, and summary indicators that serve as a foundation for the rating methodology and scores are calculated at every level of the hierarchy using specific scoring and standardization rules, as

²⁰⁹ “CMS Bulletin on display of Quality Rating System (QRS) star ratings and Qualified Health Plan (QHP) Enrollee Survey results for QHPs offered through Exchanges (often called the Health Insurance Marketplace),” August 15, 2019. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf>.

²¹⁰ See, for example, 78 FR 69418.

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described in the annual QRS and QHP Enrollee Survey Technical Guidance.²¹¹ We believe that a simplified QRS hierarchy will support alignment with other CMS quality reporting programs and help the overall quality score be more reflective of the performance of individual survey and clinical quality measures within the QRS. For example, the Medicare Star Ratings framework consists of measures, domains, summary ratings and an overall rating.²¹² In addition, we believe a simplified hierarchy, in combination with additional methodology modifications we are considering (for example, explicit weights at the measure level) will help stabilize ratings across years.²¹³ We seek comment specifically on which level or levels of the QRS hierarchy should be removed (for example, the composite level or the domain level).

In addition, to further support transparency of QHP quality data and to empower stakeholders including consumers, states, issuers and researchers with valuable information related to enrollee experience with QHPs, we propose to make the full QHP Enrollee Survey results publicly available in an annual Public Use File (PUF). Currently, we post on HealthCare.gov some enrollee experience results in the form of a quality rating for Member Experience and Plan Administration that make up part of the overall rating for QHPs.²¹⁴ The Member Experience rating is based on a select number of survey measures from the QHP Enrollee Survey. The Plan Administration rating is based on a select number of survey measures and clinical quality measures. To promote transparency of data to the public, we already post

²¹¹ “The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2021,” September 2020. Available at <https://www.cms.gov/files/document/quality-rating-system-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf>.

²¹² “Medicare 2019 Part C & D Star Rating Technical Notes,” October 10, 2019. Available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10-2019.pdf>.

²¹³ CMS anticipates continuing to propose methodology refinements to the QRS and QHP Enrollee Survey through the Call Letter process.

²¹⁴ A rating for Medical Care is the other component of the overall rating.

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QRS PUFs every year for QHP issuers operating in all Exchange types that were eligible to receive quality ratings. As we stated in the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule, we have been considering different ways to make QHP quality data, including QHP Enrollee Survey results, publicly available and accessible to researchers, consumer groups, states and other entities.²¹⁵ Similar to the QRS PUFs, we propose to post a QHP Enrollee Survey PUF annually, beginning with the 2021 QHP Enrollee Survey results and during the 2022 open enrollment period, that would include the score and proportion of responses (for example, the percentage of respondents answering “Never” or “Sometimes”) for every survey question and composite as well as demographic information such as employment status, race and ethnicity, and age at the reporting unit and national level to facilitate data transparency.

We solicit comment on this proposal.

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

In the 2014 Payment Notice, we established provisions related to the confirmation and dispute of payment and collection reports. These policies were finalized under the assumption that all issuers that receive APTCs would generally be able to provide these confirmations or disputes automatically to HHS. However, HHS has found that many issuers prefer to research payment errors and use enrollment reconciliation and disputes to update their enrollment and payment data, and may be unable to complete this research and provide confirmation or dispute of their payment and collection reports within 15 days, the timeline established by the 2014 Payment Notice.

²¹⁵ 79 FR at 30311.

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In the 2021 Payment Notice, we amended § 156.1210(a) to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow all issuers who receive APTCs more time to research, report, and correct inaccuracies through other channels. The longer timeframe also allows for the processing of reconciliation updates, which may resolve potential disputes. Additionally, at § 156.1210, we removed the requirement at paragraph (a) that issuers actively confirm payment accuracy to HHS each month, as well as the language in paragraph (b) regarding late filed inaccuracies. Instead, we amended paragraph (b) to require an annual confirmation from issuers that the amounts identified in the most recent payment and collections report for the coverage year accurately reflect applicable payments owed by the issuer to the federal government and the payments owed to the issuer by the federal government, or that the issuer has disputed any identified inaccuracies, after the end of each payment year, in a form and manner specified by HHS.

Since finalizing these changes, HHS's experience has shown that some data inaccuracies reasonably will be identified after the 90-day reporting window. For example, issuers might receive notification of an Exchange Eligibility Appeals adjudication after the 90-day submission window. Additionally, some issuers are directed to update their enrollment and payment data after an HHS data review or audit which may occur after this 90-day window. In such instances it is in the interest of HHS, issuers, and enrollees to accept the late reporting of data inaccuracies. As such, we propose to amend § 156.1210 by redesignating current § 156.1210(b) to § 156.1210(d) and adding new § 156.1210(b) to establish a process for issuers to report enrollment or payment data changes in these situations.

We clarify that this proposed flexibility does not reduce an issuer's obligation to make a good faith effort to identify and promptly report discrepancies within the 90-day reporting

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window established under § 156.1210(a). Issuers can demonstrate good faith by sending regular and accurate enrollment reconciliation files and timely enrollment disputes throughout the applicable enrollment calendar year, making timely and regular changes to enrollment reconciliation and dispute files to correct past errors, and by reaching out to HHS and responding timely to HHS outreach to address any issues identified. With respect to inaccuracies identified after the end of the applicable 90-day period, we propose to work with the issuer to resolve the inaccuracy if the issuer promptly notifies HHS, in a form and manner specified by HHS, no later than 15 days after identifying the inaccuracy. The failure to identify the inaccuracy in a timely manner in these situations must not have been due to the issuer's misconduct or negligence. For example, issuers must regularly submit quality monthly enrollment reconciliation files as required under § 156.265(f), and should regularly review monthly enrollment reconciliation files so that disputes are submitted in the 90-day reporting window. Disputes submitted after the expiration of the reporting window as a result of an issuer's failure to conduct these activities in a timely manner would not satisfy the good faith standard. We propose to codify these criteria at new proposed § 156.1210(b)(1) and (2).

Additionally, we propose to add paragraph (c) to allow the reporting of data inaccuracies after the 90-day period up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is later. We believe this deadline will provide issuers with enough time to report any data inaccuracies discovered after the 90-day submission window, while providing a reasonable end date by which HHS, issuer and other stakeholders can consider the records for a particular benefit year closed.

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We note that, pursuant to section 1313(a)(6) of the PPACA, “[p]ayments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729 et seq.) if those payments include any Federal funds.” As such if an issuer has an obligation to pay back APTCs, the issuer could be liable under the False Claims Act for knowingly and improperly avoiding the obligation to pay. We propose to codify in § 156.1210(c)(3), that, if a payment error is discovered after the 3-year or end of audit reporting deadline, the issuer is obligated to notify HHS and repay any overpayment. However, HHS will not pay the issuer after the 3-year or end of audit reporting deadline for any underpayments discovered.

We further clarify that the requirements of § 156.1210 apply to all issuers who receive APTCs, including issuers in State Exchanges. We seek comment on all aspects of this proposal, including its impact on the State Exchanges’ ability to resolve disputes and report payment adjustments to HHS in this timeframe.

We solicit comment on these proposals.

13. Payment and Collection Processes (§ 156.1215)

In the 2015 Payment Notice, HHS established a monthly payment and collections cycle for insurance affordability programs, user fees, and premium stabilization programs. As discussed above, we propose to eliminate state user fee collection flexibility that HHS had previously offered to states in 2017 Payment Notice, and propose to conforming amendments to remove the reference to “State” governments from paragraph (b). We seek comment on this proposal.

14. Administrative Appeals (§ 156.1220)

As detailed earlier in this preamble, we previously established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain

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PPACA programs, including the calculation of risk adjustment charges, payments and user fees. This process also applies to issuer disputes of the findings of a second validation audit (if applicable) as a result of HHS-RADV for the 2016 benefit year and beyond.²¹⁶ As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the initial validation audit and second validation audit will receive a Second Validation Audit Findings Report and therefore have the right to appeal the second validation audit findings. In this rule, we propose to amend § 156.1220(a)(1)(vii) to add “if applicable” when discussing an issuer’s ability to appeal the findings of the second validation audit to more clearly capture this limitation as part of the regulation, consistent with the existing language at § 153.630(d)(2) and the previously finalized policy. We propose a similar amendment in this rule to § 153.630(d)(3).

We also propose amendments to § 156.1220(a)(3) to clarify that the 30-calendar day timeframe to file a request for reconsideration of second validation audit findings (if applicable) or the risk score error rate calculation would be 30 calendar days from the applicable benefit year’s Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers. To capture this clarification, we propose to create a new proposed § 156.1220(a)(3)(ii) to specify the timeframe for filing a request for reconsideration for a risk adjustment payment or charge, including an assessment of risk adjustment user fees. This new proposed regulatory provision maintains the language that establishes a 30 calendar day window for these appeals that begin on the date of notification under § 153.310(e). We also propose to create a new proposed § 156.1220(a)(3)(iii) to separately address the timeframe for filing a request for reconsideration of second validation audit findings or the risk score error rate calculation and to add the phrase “if applicable” to more clearly capture the limitation on the

²¹⁶ See 45 CFR 156.1220(a)(1)(vii).

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ability to appeal second validation audit findings. To accommodate these two new proposed paragraphs, we also propose to amend § 156.1220 to redesignate paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively. We seek comment on these proposals.

15. Enrollment process for qualified individuals (§ 156.1240)

Under § 156.1240(a), QHP issuers are required to accept a variety of payment methods so that individuals without a bank account or a credit card will have readily available options for making monthly premium payments. Specifically, paragraph (a)(1) requires QHP issuers to follow the premium payment process established by an Exchange in accordance with § 155.240. Paragraph (a)(2) requires QHP issuers to accept for all payments in the individual market, at a minimum, paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards as methods of payment and present all payment method options equally for a consumer to select their preferred payment method. We propose to add new paragraph (a)(3) to require individual market QHP issuers to also accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA.

We have received questions indicating that there is some confusion over whether issuers must accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA. Individual coverage HRAs are a new type of health reimbursement arrangement that employers may offer to employees as of January 1, 2020.²¹⁷ In general, employers may offer individual coverage HRAs to their employees as a means of providing tax-advantaged reimbursements for medical care expenses, including premiums for individual health insurance coverage that they purchase for themselves and their families. QSEHRAs are another new type of HRA, established

²¹⁷ See 84 FR 28888.

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by the 21st Century Cures Act, enacted December 13, 2016, that qualified small employers can provide to their employees.²¹⁸ As explained in the final rule that adopted implementing regulations for individual coverage HRAs, certain aspects of which apply to QSEHRAs (final HRA rule),²¹⁹ reimbursement may include employee-initiated payments made through use of financial instruments, such as pre-paid debit cards, as well as direct payments, individual or aggregate, by the employer, employee organization, or other plan sponsor to the health insurance issuer.²²⁰

Consistent with the final HRA rule, we propose to add a new § 156.1240(a)(3) to require issuers offering individual market QHPs to accept payments of premiums that are received directly from an individual coverage HRA or QSEHRA that are made on behalf of an enrollee who is covered by the individual coverage HRA or QSEHRA. We propose that QHP issuers would be required to accept such payment when they are made using a method of payment described in §156.1240(a)(2). We recognize some individual coverage HRAs and QSEHRAs prefer to make aggregate payments on behalf of multiple employees to a QHP issuer. We encourage QHP issuers to work with employers and administrators of individual coverage HRAs and QSEHRAs to facilitate this method of payment, as we believe this approach can ease administration of individual coverage HRAs and QSEHRAs. However, we are not proposing to require QHP issuers to accept payments from individual coverage HRAs or QSEHRAs when made using a form of payment that is not described in §156.1240(a)(2). This proposal would help ensure that individual coverage HRAs or QSEHRAs operate as intended, and would address

²¹⁸ Pub. L. 114-255 (Dec. 13, 2016).

²¹⁹ 84 FR 28888 (June 20, 2019).

²²⁰ See 84 FR at 28950—51 (“[E]mployer funds paid from an HRA go directly to a participant or a health insurance issuer because the economic substance of the transaction is the same—that is, the funds are being used to discharge an employee’s premium payment obligations.”)

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potential stakeholder confusion regarding whether QHP issuers must accept payments made from individual coverage HRAs or QSEHRAs.

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

1. Definitions (§ 158.103)

To ensure program integrity, we propose to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes.

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.

In the May 14, 2020 **Federal Register** (85 FR 29164), we finalized amendments to the MLR rules at § 158.140(b)(1)(i) to require issuers to deduct from MLR incurred claims not only prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer and any prescription drug rebates and other price concessions received and retained by a PBM or other entity providing pharmacy benefit management services to the issuer. The applicability date for that amendment is the 2022 MLR reporting year (MLR reports filed in 2023).

During the regulatory process, we received numerous comments requesting HHS to codify and align the definition of prescription drug rebates and other price concessions that are

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reported by issuers for MLR purposes with the definition in section 1150A of the Act, as added by the PPACA,²²¹ which requires QHP issuers and PBMs to report certain prescription drug benefit information to HHS. The reference to rebates, discounts, and price concessions in section 1150A(b)(2) of the Act excludes bona fide service fees paid to PBMs by drug manufacturers or issuers. Under section 1150A of the Act, bona fide service fees are fees negotiated by PBMs that include but are not limited to “distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).” Section 156.295, implementing section 1150A of the Act, defines bona fide services fees as “fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.”

In light of these comments and the delayed applicability date of the amendment to § 158.140(b)(1)(i), we did not finalize a definition of “prescription drug rebates” or “price concession” in that rulemaking. Rather, we indicated that we would consider codifying the definition of prescription drug rebates and other price concessions through separate rulemaking in advance of the applicability date for these new reporting requirements.

We propose to amend § 158.103 to add a definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate

²²¹ The requirements of section 1150A with respect to QHP issuers are codified at § 156.295. In this proposed rule, we propose to amend that regulation and to codify the requirements with respect to PBMs at a new 45 CFR part 184.

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calculation purposes pursuant to § 158.140(b)(1)(i). We believe that codifying and clarifying the definition of prescription drug rebates and other price concessions will allow issuers to more accurately report the costs associated with enrollees' prescription drug utilization for purposes of the MLR calculation. This approach would also promote consistency in reporting across issuers. Therefore, we propose to amend the MLR rules to add the definition for prescription drug rebates and other price concessions to § 158.103 and to clarify that this term excludes bona fide service fees, consistent with how such fees are described in § 156.295. We propose that this provision become applicable beginning with the 2022 MLR reporting year (MLR reports filed in 2023), which aligns with the applicability date of the amendment to § 158.140(b)(1)(i) and should provide issuers with adequate time to adjust contracts with entities providing pharmacy benefit management services to provide transparency regarding prescription drug rebates and other price concessions they receive from drug manufacturers.

We seek comment on this proposal.

2. Premium Revenue (§ 158.130)

Section 2718(a) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary that details the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under health insurance coverage and on activities that improve healthcare quality. Section 158.130 specifies the reporting requirements with regard to earned premium, which must include all monies paid by a policyholder or subscriber as a condition of receiving coverage from the issuer, with certain adjustments.

In the August 4, 2020 guidance, Temporary Policy on 2020 Premium Credits Associated with the COVID-19 PHE, CMS adopted a temporary policy of relaxed enforcement to allow

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issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage to support continuity of coverage for individuals, families and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 PHE.²²² On September 2, 2020, HHS issued an interim final rule on COVID-19 wherein we set forth MLR data reporting and rebate requirements for issuers offering temporary premium credits for 2020 coverage.²²³ For the 2021 MLR reporting year²²⁴ and beyond, we propose to adopt these MLR data reporting and rebate requirements for all health insurance issuers in the individual and small group markets²²⁵ who elect to offer temporary premium credits during a PHE declared by the Secretary of HHS (declared PHE) in situations in which HHS issues guidance announcing its adoption of a similar temporary policy of relaxed enforcement to allow such issuers to offer temporary premium credits during the declared PHE.²²⁶

We propose that for purposes of § 158.130, issuers must account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, consistent with any technical guidance set forth in the

²²² “Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency,” August 4, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

²²³ 85 FR 54820 (Sept. 2, 2020).

²²⁴ The MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer. See 45 CFR 158.103. The 2021 MLR reporting year refers to the MLR reports that issuers must submit for the 2021 benefit year by July 31, 2022. See 45 CFR 158.110(b).

²²⁵ While this proposed rule, the interim final rule on COVID-19 and the August 4, 2020 guidance focus on the individual and small group markets, to remove the barriers in support of issuers offering these premium credits to enrollees impacted by a PHE declared by the Secretary of HHS, we note that issuers in the large group market may also, when consistent with state law, offer temporary premium credits and should similarly report the lower, adjusted amount that accounts for the premium credits for MLR purposes.

²²⁶ The Secretary of HHS may, under section 319 of the PHS Act, determine that: a) a disease or disorder presents a public health emergency; or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

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applicable year's MLR Annual Reporting Form Instructions,²²⁷ when such credits are permitted by HHS. Specifically, as clarified in the interim final rule on COVID-19, we propose that the amount of temporary premium credits²²⁸ would constitute neither collected premium nor due and unpaid premium described in the MLR Annual Reporting Form Instructions for purposes of reporting written premium (which is a component of earned premium). Consequently, under this proposal, issuers who offer temporary premium credits during a declared PHE would report as earned premium for MLR and rebate calculation purposes the actual, reduced premium paid when such credits are permitted by HHS.

We request comment on this proposal.

3. Rebating Premium if the Applicable Medical Loss Ratio Standard is Not Met (§ 158.240)
- Section 2718(b) of the PHS Act, and the implementing regulations at §§ 158.210 and 158.240, require an issuer to provide an annual rebate to enrollees, on a pro rata basis, if the ratio of the amount of premium revenue expended by the issuer on reimbursement for clinical services provided to enrollees under the health insurance coverage and for activities that improve health care quality to the total amount of premium revenue (excluding federal and state taxes and licensing or regulatory fees) is less than 80 percent in the individual and small group markets and 85 percent in the large group market. In order to determine whether its MLR met the applicable standard, § 158.110(b) requires an issuer to submit to CMS, by July 31 of the year following the end of the MLR reporting year, an MLR Annual Reporting Form concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued.

²²⁷ Available at https://www.cms.gov/ccio/Resources/Forms-Reports-and-OtherResources/index#Medical_Loss_Ratio.

²²⁸ MLR rebates provided in the form of premium credits are different than the temporary premium credits such as those outlined in the August 4, 2020 guidance issued by CMS. When MLR rebates are provided in the form of premium credits, issuers must continue to report the full amount of earned premium and may not reduce it by the amount of MLR rebates provided in form of premium credits, as required by § 158.130(b)(3).

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Section 158.241 permits an issuer to provide MLR rebates in the form of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium. Issuers that choose to provide a rebate via a lump-sum check or lump-sum reimbursement to the account used to pay the premium must issue the rebate *no later than* September 30 following the end of the MLR reporting year pursuant to § 158.240(e). Issuers that elect to provide rebates in the form of a premium credit must apply the rebate to the first month's premium that is due *on or after* September 30 following the MLR reporting year pursuant to § 158.241(a)(2). This section also requires that when the rebate is provided in the form of a premium credit and the total amount of the rebate owed exceeds the premium due for October, any excess rebate amount must be applied to succeeding premium payments until the full amount of the rebate has been credited. Pursuant to § 158.240(f), an issuer that fails to pay a rebate owed to an enrollee in accordance with the applicable timeframes established in §§ 158.240(e) and 158.241(a)(2) is required to pay the enrollee the required rebate plus interest, at ten percent annually, accruing from the date payment was due.

On June 12, 2020, we announced a temporary policy of relaxed enforcement to allow issuers to prepay to enrollees a portion or all of the estimated MLR rebate for the 2019 MLR reporting year in the form of a premium credit, to the extent consistent with state law or other applicable state authority, in order to support continuity of coverage for enrollees who may struggle to pay premiums because of illness or loss of income resulting from the COVID-19 PHE.²²⁹ This temporary policy of relaxed enforcement was limited to issuers that choose to

²²⁹ “Temporary Period of Relaxed Enforcement for Submitting the 2019 MLR Annual Reporting Form and Issuing MLR Rebates in Response to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.” (June 12, 2020). Available at <https://www.cms.gov/files/document/Issuing-2019-MLR-Rebates-in-Response-to-COVID-19.pdf>.

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prepay a portion or all of their estimated 2019 MLR rebate in the form of a premium credit, as the current rules do not prohibit issuers paying rebates in the form of a lump-sum check or lump-sum reimbursement to the account used to pay the premium from prepaying a portion or all of their rebates as long as the full rebate amount owed to an enrollee is paid to that enrollee *no later than* September 30 following the end of the MLR reporting year.²³⁰

Given the benefits experienced by enrollees in light of this temporary policy of relaxed enforcement during the COVID-19 PHE and our desire to continue to provide this flexibility for future years, we propose to amend § 158.240 by adding paragraph (g), which would explicitly allow issuers to prepay a portion or all of their estimated rebates to enrollees for any MLR reporting year regardless of the form in which they are paid. We believe that enrollees would generally benefit from the ability to receive estimated rebates earlier than contemplated by the timelines currently codified in §§ 158.240(e) and 158.241(a)(2) and prior to issuers submitting their MLR Annual Reporting Forms pursuant to § 158.110(b). We also propose to require that issuers that choose to prepay a portion or all of their estimated rebates do so for all eligible enrollees in a given state and market in a non-discriminatory manner.

In addition, under the current rules, an issuer that prepays a portion or all of its estimated rebate in the form of a lump-sum check, or if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium, and subsequently determines that such prepayment is less than the total rebate owed to an enrollee would have to incur the costs of disbursing rebates twice: first to disburse the prepaid rebate amount, and again to disburse the remaining rebate amount by the deadlines set forth in §§ 158.240(e) and 158.241(a)(2). To reduce the regulatory burden on issuers and incentivize issuers

²³⁰ 45 CFR 158.240(e).

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to deliver rebates to enrollees sooner, we propose to add to the proposed new § 158.240(g) a safe harbor under which an issuer that prepays at least 95 percent of the total rebate owed to enrollees in a given state and market for a given MLR reporting year by the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) may, without penalty or late payment interest under § 158.240(f), defer the payment of any remaining rebate owed to enrollees in that state and market until the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) for the following MLR reporting year. This would enable such an issuer to maintain a single rebate disbursement cycle per year. Furthermore, the issuer would be able to combine payment of rebates remaining after prepayment with the rebates for the following MLR reporting year for enrollees who are enrolled with the issuer during both years. Enrollees who are no longer enrolled with the issuer the following year would receive only the rebates remaining after prepayment, but the issuer would still benefit by disbursing these amounts as part of the issuer's regular rebate disbursement process in the following year. At the same time, the proposed safe harbor would ensure that enrollees continue to receive most of the rebate within the regular timeframe, as issuers that prepay less than 95 percent of the total rebate owed to enrollees for a given MLR reporting year would continue to be required to provide the enrollees with the remaining portion of the rebate owed in accordance with the timeframes set forth in §§ 158.240(e) and 158.241(a)(2) for the current MLR reporting year. To further ensure that enrollees do not regularly receive reduced rebates as a result of prepayments, we also propose that under this safe harbor, the rebate amount remaining after prepayment would not be treated as *de minimis*, regardless of how small the remaining amount is. That is, the *de minimis* provisions in § 158.243 continue to apply only if the total rebate (the sum of the prepaid amount and any

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amount remaining after prepayment) owed to an enrollee for a given MLR reporting year is below the applicable threshold.

We note that § 158.250 requires issuers to provide a notice of rebates at the time any rebate is provided, which includes both rebate prepayments and payments of rebates remaining after prepayment. We intend to modify the ICRs approved under OMB Control Number 0938-1164 to add modified standard notices that can be used by issuers that elect to prepay rebates under the proposed new § 158.240(g). We also intend to revise the MLR Annual Reporting Form Instructions to clarify that an issuer that prepays a portion or all of its estimated rebate and subsequently determines that the amount of such prepayment is more than the total rebate owed to an enrollee for that MLR reporting year and that does not recoup the overpayment from the enrollee, may include the overpayment in its rebate payments reported for purposes of calculating the optional limit on the payable rebates under § 158.240(d). We additionally intend to revise the MLR Annual Reporting Form Instructions to clarify how issuers that prepay estimated rebates must report such prepayments.

We propose that this amendment to create new § 158.240(g) would be applicable beginning with the 2020 MLR reporting year (MLR reports filed in 2021). We seek comment on this proposal, including the proposed applicability date.

4. Form of Rebate (§ 158.241)

As discussed in the prior section of this preamble, § 158.241 permits an issuer to provide MLR rebates in the form of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium. Under § 158.240(e), issuers that choose to provide a rebate via a lump-sum check or lump-sum reimbursement to the account used to pay the premium must issue the rebate

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no later than September 30 following the end of the MLR reporting year. In contrast, § 158.241(a)(2) provides that issuers that elect to provide rebates in the form of a premium credit must apply the rebate to the first month's premium that is due *on or after* September 30 following the MLR reporting year, and that when the rebate is provided in the form of a premium credit and the total amount of the rebate owed exceeds the premium due in October, any excess rebate amount must be applied to succeeding premium payments until the full amount of the rebate has been credited.

Given the proposed addition of § 158.240(g) discussed in the prior section, the fact that an issuer may wish to provide rebates in the form of a premium credit earlier than October, and the desire to reduce the regulatory burden and enable enrollees to receive the benefit of rebates sooner, we propose to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to the date that the rules currently provide. Specifically, we propose to amend § 158.241(a)(2) to specify that when provided in the form of premium credits, rebates must be applied to premium that is due no later than October 30 following the MLR reporting year. We propose that this amendment would be applicable beginning with the 2020 MLR reporting year (MLR reports due in 2021).

We seek comment on this proposal, including on the proposed applicability date.

G. Part 184 – Pharmacy Benefit Manager Standards under the Affordable Care Act

1. Prescription Drug Distribution and Cost Reporting by Pharmacy Benefit Managers (§§ 184.10 and 184.50)

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PBMs are third-party administrators that manage the prescription drug benefit for a contracted entity.²³¹ This administration typically involves processing claims, maintaining drug formularies, contracting with pharmacies for reimbursement for drugs dispensed, and negotiating prices with drug manufacturers.²³²

The role of PBMs in the prescription drug landscape, including any impact on the rising cost of prescription drugs, is not well understood.²³³ For example, PBMs generate revenue, in part, by retaining the difference between the amount paid by the health plan for prescription drugs and the amount the PBM reimburses pharmacies, a practice commonly referred to as “spread pricing.” While estimates report the increasing prevalence of spread pricing in private health insurance plans,²³⁴ detailed data on the practice has generally not been collected by plans or by any state or federal regulatory body.

We propose to add part 184 to 45 CFR subchapter E to codify in regulation the statutory requirement that PBMs under contract with QHP issuers report the data described at section 1150A(b) of the Act to the Secretary and to each QHP for which the PBM administers the prescription drug benefit.

At proposed § 184.10(a)(1), we explain that new part 184 is based on section 1150A of the Act. At proposed § 184.10(b), we propose that the scope of new part 184 establishes standards for PBMs that administer prescription drug benefits for health insurance issuers which offer QHPs with respect to the offering of such plans. We also propose definitions for part 184 at

²³¹ PBMs contract with a variety of health plans, including, but not limited to, individual and small group health plans, large group and self-insured plans, and Medicare Part D drug plans. In this section, we only reference PBMs that contract with a health insurance company to administer the prescription drug benefit for QHPs.

²³² “Pharmacy Benefit Managers,” Health Affairs Health Policy Brief, September 14, 2017.

Available at <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/>.

²³³ Elizabeth Seeley and Aaron S. Kesselheim. “Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead,” Commonwealth Fund, March 2019. Available at <https://doi.org/10.26099/n60j-0886>.

²³⁴ See “The Prescription Drug Landscape, Explored.” Available at https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf.

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new § 184.20. Except for the definition of pharmacy benefit manager, these proposed definitions would codify terms already in use in parts 144 and 155 of subchapter B of subtitle A of title 45 of the Code of Federal Regulations.

As part of the PPACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a state under section 1311 of the PPACA²³⁵ to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section 1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.²³⁶

In the 2012 Exchange Final Rule, we codified the requirements of section 1150A of the Act, as it applies to QHPs, at § 156.295.²³⁷ On January 1, 2020²³⁸ and on September 11, 2020²³⁹, we published **Federal Register** notices and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act, as referenced earlier. As noted earlier in this preamble, we propose to revise § 156.295 to

²³⁵ This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the PPACA. *King v. Burwell*, 576 U.S. 988 (2015).

²³⁶ As noted earlier in this preamble, the purposes are: as the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the PPACA.

²³⁷ Section 1150A(a)(1) also authorizes the collection of data from PBMs that manage prescription drug coverage under contract with a Prescription Drug Plan sponsor of a prescription drug plan or a Medicare Advantage organization offering a Medicare Advantage prescription drug plan.

²³⁸ 85 FR 4993 through 4994.

²³⁹ 85 FR 56227 through 56229.

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state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs, the QHP issuer will report the data required by section 1150A of the Act to HHS.

We propose to add § 184.50(a) to state that where a PBM contracts with an issuer of QHPs to administer the prescription drug benefit for their QHPs, the PBM is required to report the data required by section 1150A(b) of the Act to the QHP and to the Secretary, at such times, and in such form and manner, as the Secretary shall specify. While we acknowledge that this section applies to both the QHP issuer and their PBMs to report this data, we propose to implement section 1150A to require PBMs to report this data directly to the Secretary, and only to require the QHP issuer to report the data only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs, as further discussed in the preamble to § 156.295 in this proposed rule.

We propose to add § 184.50(a)(1) through (3) to require these PBMs to report the data described at section 1150A(b) of the Act to the Secretary. The data proposed to be collected, as required by section 1150A, are: the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), that is paid by the health benefits plan or PBM under the contract²⁴⁰; the aggregate amount, and the type of rebates, discounts, or price concessions (excluding *bona fide* service fees, which include but are not

²⁴⁰ As stated above in the preamble for § 156.295, section 1150A(b)(1) requires the Secretary to collect data by pharmacy type. However, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is a not standard classification currently captured in industry databases or files. To reduce burden, we are not proposing to collect data by pharmacy type at this time. We intend to collect this information at a time when the imposition of such a requirement would pose reasonable burden. We seek comment on ways that we may impose the collection of data by pharmacy type in the future without imposing unreasonable burden on the industry.

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limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs²⁴¹) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies (spread pricing), and mail order pharmacies, and the total number of prescriptions that were dispensed.

At new § 184.50(b) and (c), we also propose to codify the confidentiality and penalty provisions that appear at § 1150A(c) and (d) to PBMs which administer the prescription drug benefits for QHP issuers.

We seek comment on these proposals.

IV. Provisions of the Proposed Rule for State Innovation Waivers – Department of Health and Human Services and Department of the Treasury

A. 31 CFR Part 33 and 45 CFR Part 155 – State Innovation Waivers

1. Section 1332 Application Procedures (31 CFR 33.108 and 45 CFR 155.1308), Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320), and Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

Section 1332 of the PPACA permits states to apply for a State Innovation Waiver (also referred to as a section 1332 waiver or State Relief and Empowerment Waiver) to pursue

²⁴¹ This definition of bona fide service fees was finalized at § 156.295 in the 2012 Exchange Final Rule at 77 FR 18432. There, we finalized this definition to align with the definition of bona fide service fees finalized in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule. See 77 FR 22072 at 22093.

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innovative strategies for providing their residents with access to higher value, more affordable health coverage. The overarching goal of section 1332 waivers is to give all Americans the opportunity to obtain high value and affordable health coverage regardless of income, geography, age, sex, or health status, while simultaneously empowering states to develop health coverage strategies that best meet the needs of their residents. In this proposed rule, the Departments seek to provide states with consistency and predictability by codifying the Departments' long-standing policy published in the **Federal Register** in 2018, regarding how the Departments will apply section 1332 of the PPACA to determine whether applications for section 1332 waivers will be approved.

Under section 1332 of the PPACA, the Secretaries may exercise their discretion to approve a request for a section 1332 waiver only if the Secretaries determine that the proposal for the section 1332 waiver meets the following four requirements (referred to as the statutory guardrails): (1) The proposal will provide coverage that is at least as comprehensive as coverage defined in PPACA section 1302(b) and offered through Exchanges established by title I of PPACA, as certified by the Office of the Actuary of CMS, based on sufficient data from the state and from comparable states about their experience with programs created by the PPACA and the provisions of the PPACA that would be waived; (2) the proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided under title I of PPACA; (3) the proposal will provide coverage to at least a comparable number of the state's residents as would be provided under title I of PPACA; and (4) the proposal will not increase the federal deficit. The Secretaries retain their discretionary authority under section 1332 to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrails.

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The Departments are also responsible under section 1332 of the PPACA for monitoring a waiver's compliance with the statutory guardrails and for conducting evaluations to determine the impact of the waiver. Specifically, section 1332 of the PPACA requires that the Secretaries provide for and conduct periodic evaluations of approved section 1332 waivers. The Secretaries must also provide for a process under which states with approved waivers must submit periodic reports concerning the implementation of the state's waiver program.

In October 2018, the Departments issued the 2018 Guidance,²⁴² which provides additional guidance for states that wish to submit section 1332 waiver proposals regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. The 2018 Guidance also includes information regarding how the Departments will apply the section 1332 statutory guardrails to evaluate whether a waiver is approvable. Section 1332 of the PPACA and the 2018 Guidance empower states to address problems with their individual insurance markets and increase coverage options for their residents, and to encourage states to evaluate and adopt innovative strategies to reduce future overall health care spending. Together, the statutory guardrails and the 2018 Guidance provide states a reliable roadmap to follow in designing section 1332 waiver programs that will promote a stable health insurance market that offers more choice and affordability to state residents.

In this proposed rule, the Departments seek to provide certainty to states that the requirements and expectations of the section 1332 program will not change abruptly, or without notice to states and the public and an opportunity to comment, during a period in which states are doing the work to prepare a section 1332 waiver proposal that would satisfy the statutory

²⁴² 83 FR 53575 (Oct. 24, 2018).

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guardrails or during a state's approved waiver period. Specifically, the Departments propose to incorporate the 2018 Guidance in full in the regulations governing section 1332 waiver application procedures, monitoring and compliance, and periodic evaluation requirements. The Departments are of the view that this proposal would give states greater certainty regarding how the Departments will apply section 1332's statutory guardrails when determining whether a state's waiver proposal can receive approval by the Departments and remain in compliance.

31 CFR 33.108 and 45 CFR 155.1308 specify the application procedures a section 1332 waiver proposal must meet to be approved by the Secretaries. Under these regulations, an application for initial approval of a section 1332 waiver will not be considered complete unless the application complies with the application procedures under 31 CFR 33.108(f) and 45 CFR 155.1308(f), including written evidence of the state's compliance with the public notice requirements set forth in 31 CFR 33.112 and 45 CFR 155.1312. Furthermore, an application must provide a comprehensive description of the enacted state legislation and program to implement a plan meeting the requirements for a waiver under section 1332; a copy of the enacted state legislation authorizing such waiver request; a list of the provisions of law that the state seeks to waive including a brief description of the reason for the specific request; and the analyses, actuarial certifications, data, assumptions, targets and other information sufficient to provide the Secretaries with the necessary data to determine that the state's proposed waiver meets the statutory guardrails. The 2018 Guidance provides supplementary information about the requirements that must be met for the approval of a State Innovation Waiver, the Secretaries' application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. The 2018 Guidance also describes ways in which a section 1332 state plan may meet section 1332 requirements in order to be eligible to be

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approved by the Secretaries, clarifying the adjustments the Secretaries may make to maintain federal deficit neutrality, and allowing for states to use existing legislative authority to authorize section 1332 waivers in certain scenarios. The Departments are of the view that using consistent application requirements will encourage more states to pursue waivers without the worry that some of the rules may change after they have submitted a waiver application. Furthermore, by referencing and incorporating the full guidance into regulations, this proposal would allow states to plan for future waiver applications. The Departments are of the view that this proposal will provide certainty to states as they invest significant state resources towards submission of a section 1332 waiver and implementation of a section 1332 waiver, particularly waivers that require multiyear preparation.

This proposed rule proposes to incorporate the 2018 Guidance in full in the Departments' monitoring and compliance regulations at 31 CFR 155.1320 and 45 CFR 155.1320. Specifically, under the current requirements the Secretaries reserve the right to suspend or terminate a waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the state materially failed to comply with the terms and conditions of the waiver. The Departments will review and, when appropriate, investigate documented complaints that the state is failing to materially comply with requirements specified in the approved waiver and the specific terms and conditions (STCs) for the approval of the waiver signed by the Departments and the state. In addition, the Departments will promptly share with the state any complaint that they may receive and will notify the state of any applicable monitoring and compliance issues. Additionally, states with approved section 1332 waivers must comply with all applicable federal laws and regulations (unless specifically waived) and must come into compliance with any changes in federal law or regulations affecting section 1332 waivers. The Departments are of the view that

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this proposal to incorporate the full 2018 Guidance in the monitoring and compliance requirements will provide certainty regarding how the Departments will evaluate and review section 1332 waiver programs, as states submit information concerning the implementation of the waiver program.

This proposed rule also proposes to incorporate the 2018 Guidance in full in the periodic evaluation requirements regulations at 31 CFR 33.128 and 45 CFR 155.1328. Under current requirements, the Departments are responsible for evaluating the waiver using federal data, information reported by states, and the waiver application itself to ensure that the Departments can exercise appropriate oversight of the approved waiver. Per 31 CFR 33.120(f) and 45 CFR 155.1320(f), the state must fully cooperate with the Departments or an independent evaluator selected by the Departments in consultation with the state, to undertake an independent evaluation of any component of the section 1332 waiver. As part of this required cooperation, the state must submit all requested data and information to the Departments or the independent evaluator. The state generally must meet the statutory requirements in each year that the waiver is in effect, as such the primary focus of the periodic evaluations will be the four statutory guardrails. However, the Departments will consider the longer-term impacts of a state's proposal. The Departments are of the view that this proposal to incorporate the full 2018 Guidance in the periodic evaluation requirements will provide certainty regarding how the Departments will evaluate whether a section 1332 waiver may maintain its approval by the Departments. The Departments also believe that this proposal will also help states to anticipate the data that will be most relevant and helpful to the Departments' analyses of a state's compliance with the specific terms and conditions approved by the Departments.

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As such, the Departments specifically propose to revise the language in 31 CFR 33.108(f)(3)(iv), 31 CFR 33.120(a)(1), 31 CFR 33.128(a), 45 CFR 155.1308(f)(3)(iv), 45 CFR 155.1320(a)(1), and 45 CFR 155.1328(a) to incorporate the 2018 Guidance in full. The Departments are of the view that the increased certainty that would result from incorporating the full 2018 Guidance as proposed into the section 1332 implementing regulations will allow states to have greater confidence that the significant time and monetary investments necessary to plan for and submit a section 1332 waiver application will not result in wasted resources and taxpayer dollars. The Departments are also of the view that this proposed rule will help to increase state innovation, which could lead to more affordable health coverage for individuals and families in states that implement a section 1332 waiver program. The Departments seek comment on these proposals.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 11. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

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- 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 ICRs.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.²⁴³ Table 10 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 10: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr.)	Fringe Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
Compliance Officer	13-1041	\$35.03	\$35.03	\$70.06
Pharmacy Technician	29-2052	\$16.95	\$16.95	\$33.90
Secretaries and Administrative Assistants	43-6014	\$18.84	\$18.84	\$37.68
Billing and Posting Clerks	43-3021	\$19.53	\$19.53	\$39.06
Chief Executives	11-1011	\$93.20	\$93.20	\$186.40
Business Operations Specialist	13-1198	\$38.57	\$38.57	\$77.14
Computer System Analyst	15-1121	\$46.23	\$46.23	\$92.46
Computer Programmer	15-1251	\$44.53	\$44.53	\$89.06
Computer and Information Systems Manager	11-3021	\$75.19	\$75.19	\$150.38

²⁴³ See May 2019 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/oes_stru.htm.

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Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr.)	Fringe Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
General and Operations Manager	11-1021	\$59.15	\$59.15	\$118.30
Auditor	13-2011	\$38.23	\$38.23	\$76.46

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are proposing to allow state regulators to request a reduction in the calculation of risk adjustment transfers under the state payment transfer formula under § 153.320(d) for up to 3 years, beginning for the 2023 benefit year. HHS would require any state that intends to request multi-year flexibility to submit its request by August 1st of the calendar year that is 2 calendar years prior to the beginning of the first benefit year of its request. HHS would reserve the right to require states with approved multi-year reduction requests to submit supplemental evidence in any subsequent year of the request after its initial approval, in the timeframe, form, and manner specified by HHS, and would also reserve the right to terminate or modify an approved multi-year reduction request prior to its natural expiration. We propose to permit states with approved multi-year requests to withdraw their respective request before its natural expiration by notifying HHS of its requested withdrawal. We also propose to require states to inform impacted issuers of any early termination, modification, or withdrawal of a multi-year reduction request. We expect that fewer than 10 states would make these requests annually. Therefore, we believe that this collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

C. ICRs Regarding Submission of Adjusted Premium Amounts for Risk Adjustment

45 CFR 153.610 and 153.710 provide that issuers of a risk adjustment covered plan must provide HHS with access to risk adjustment data through a dedicated distributed data environment (EDGE server), in a manner and timeframe specified by HHS. We clarify that, for purposes of risk adjustment data submissions in the 2021 benefit year and beyond when a

declared PHE is in effect and HHS permits these premium credits, issuers that choose to provide

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premium credits must submit the adjusted (that is, lower) plan premiums for those months, instead of the unadjusted plan premiums. HHS would require issuers to submit adjusted plan premiums to their EDGE servers for all enrollees whom the issuer has actually provided premium credits as a reduction to the corresponding benefit year premiums. We do not believe that issuers who elect to provide these premium credits will incur additional operational burden associated with EDGE server data submissions as a result of these requirements because we expect issuers' premium reporting systems will already be configured to enable issuers to upload the billable premiums actually charged to enrollees for the applicable benefit year to the EDGE server. Additionally, the current EDGE server operational guidance for the risk adjustment program allows issuers to submit billable premium changes so there will be no changes to the data submission rules. The burden related to this information collection is currently approved under OMB control number 0938-1155 (Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals). The information collection request expires on February 23, 2021.

D. ICRs Regarding Direct Enrollment (§§ 155.220 and 155.221)

At § 155.220(c)(3)(iii), we are proposing to require web-brokers' non-Exchange websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), including a standardized disclaimer provided by the Exchange if the web-broker non-Exchange website does not facilitate enrollment in all QHPs offered through the Exchange, before assisters would be permitted to use the web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment. The Exchange would provide the exact text for this disclaimer and the language would not need to be customized.

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At § 155.220(c)(6), we propose a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission of a number of artifacts of documentation or completion of certain testing processes. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that it would take up to 2 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit the required operational data and web-broker agreement to HHS each year. We estimate that it would take up to 17 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit the required security and privacy assessment documentation to HHS. The total burden for each web-broker would be approximately 19 hours, with an equivalent cost of approximately \$1,466. Based on current web-broker participation and potential market size, we estimate that 30 web-brokers would participate. We estimate that these data collections would have an annual burden of 570 hours with a cost of approximately \$43,970.

We propose to add additional detail to the operational readiness requirement in § 155.221(b)(4) to incorporate requirements for direct enrollment entities seeking approval to use the EDE pathway. In proposed § 155.221(b)(4), we propose a direct enrollment entity must demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a

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QHP selection, which may include submission of a number of artifacts of documentation or completion of various testing or training processes. The required documentation could include business audit documentation including: notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation could also include security and privacy audit documentation including: interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; vulnerability scan results; and an agreement between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that for each direct enrollment entity it would take up to 9 hours for a Business Operations Specialist (at an hourly cost of \$77.14) to complete and submit a typical documentation package and related information to HHS each year. Based on current EDE participation and potential market size, we estimate that 77 EDE entities would participate in a manner such that they would be required to submit this type of information, and therefore, this data collection would have an annual burden of 693 hours with an annual cost of approximately \$53,458. In addition, we estimate that it would take up to 72 hours for an Auditor (at an hourly cost of \$76.46) to complete and submit a business requirements audit package for a direct enrollment entity, including audit report and testing results, to HHS. Based on current EDE participation and potential market size, we estimate that four EDE entities would participate, and therefore this data collection would have an annual burden of 288 hours with a cost of approximately \$22,020. We also estimate that it would take up to 122 hours for an Auditor (at an hourly cost of \$76.46) to complete and submit a security

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and privacy audit package for a direct enrollment entity to HHS each year. Based on current EDE participation and potential market size, we estimate that 14 EDE entities would participate, and therefore this data collection would have an annual burden of 1,708 hours with a cost of approximately \$130,594.

E. ICRs Regarding Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

We propose to revise § 156.295 and add § 184.50 to require QHP issuers or PBMs that contract with QHP issuers to report the data envisioned by section 1150A. We have not previously collected this data; therefore, the burden associated with these proposals would reflect the imposition of the burden for a new collection, and not merely the burden created by changes to existing regulatory text. On January 1, 2020²⁴⁴ and on September 11, 2020,²⁴⁵ we published notices in the **Federal Register** and solicited public comment on the burden related to these ICRs. Here, we replicate the discussion regarding burden from the information collection published in September 2020 and solicit a third round of public comment on the burden associated with this collection.

The burden associated with this collection is attributed to QHP issuers and PBMs, and the burden estimates were developed based on our previous experience with QHP information reporting activities. We are unaware of any QHP issuer that does not contract with a PBM to administer their prescription drug benefit. While we invite comment on whether any QHP issuer does not use a PBM, we do not currently estimate any burden for a QHP issuer to submit data

²⁴⁴ 85 FR 4993 through 4994.

²⁴⁵ 85 FR 56227 through 56229.

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directly. The following burden estimate reflects our expectation that all data would be submitted by PBMs.

Across all 50 states and the District of Columbia, we estimate approximately 40 PBMs would be subject to the reporting requirement. We further estimate that these PBMs, taken as a whole, annually contract with approximately 275 QHP issuers to administer the prescription drug benefit for their QHPs. We estimate that the 275 QHP issuers offer 7,000 total QHPs annually or 25.4 QHPs per QHP issuer. Thus, we estimate that each of the 40 PBMs would report data for 175 QHPs on average each year. We understand that some of these PBMs would contract with more QHP issuers than others, and as such, the reporting requirement would vary per PBM. We seek comment on the number of PBMs and the number of QHPs estimated.

Each PBM that administers pharmacy benefits for a QHP issuer would be required to complete a web form and a data collection instrument. The web form would collect data aggregated at the QHP issuer level for all plans and products offered by the QHP issuer combined. The web form would also require the reporting of an allocation methodology that is selected by the PBM to allocate data, where necessary. We would expect submitters to maintain internal documentation of the allocation methodologies chosen, as CMS may need to follow-up with the submitter to better understand the methodology.

PBMs would prepare and submit one data collection instrument per QHP issuer by Health Insurance Oversight System (HIOS) ID. Each data collection instrument would contain information regarding each plan the issuer offers. We estimate that an average PBM would report information for 5,200 NDCs for each QHP. The reports must include the data for all of the plans that the QHP issuer offered in their QHPs in the applicable plan year, even if they have no data to report for that plan year.

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Each submitter would also be required to complete an attestation which confirms the data submitted is accurate, complete, and truthful.

We estimate that 40 PBMs would submit data for this reporting requirement, each submitting data for 175 QHPs on average. For each PBM, we estimate that it would take compliance officers approximately 570 hours (for an annual cost of approximately \$39,934 at a rate of \$70.06 per hour), pharmacy technician 350 hours (for an annual cost of \$11,865 at a rate of \$33.90 per hour), secretaries and administrative assistants 175 hours (for an annual cost of \$6,594 at a rate of \$37.68 per hour), and billing and posting clerks 175 hours (for an annual cost of approximately \$6,836 at a rate of \$39.06 per hour) to prepare and submit the information and 8 hours for a chief executive (for an annual cost of approximately \$1,491.20 at a rate of \$186.40 per hour) to review the information and complete the attestation. In total, we estimate it will take a PBM approximately 1,278 hours to respond to this reporting requirement each year on average, for a total annual cost of approximately \$66,719 per PBM to report data. This estimate will vary by PBM, since each PBM will report for a different number of plans, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 40 PBMs combined to be approximately 51,120 hours or \$2,668,796.

We estimate that PBMs would incur burden to complete a one-time technical build to implement the changes necessary for this collection, which would involve activities such as planning, assessment, budgeting, contracting, and reconfiguring systems to generate data extracts that conform to this collection's requirements. We assume that this one-time burden would be incurred primarily in 2021. We estimate that, for each PBM, on average, it would take project management specialists and project management specialists and business operations specialists 500 hours (at \$77.51 per hour), computer system analysts 1,300 hours (at \$92.46 per hour),

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computer programmers 2,080 hours (at \$89.06 per hour), computer and information systems managers 40 hours (at \$150.38 per hour) and general and operations managers 50 hours (at \$118.30 per hour) to complete this task. The total one-time burden for a PBM would be approximately 3,970 hours on average, with an equivalent cost of approximately \$356,128. For all 40 PBMs, the total one-time burden would be 158,800 hours for a total cost of approximately \$14.2 million. For all 40 PBMs, the average annual burden in 2021-2023 incurred for implementation and reporting would be approximately 87,013 hours with an average annual cost of approximately \$6.5 million.

We estimate that 275 QHP issuers would need to identify for the PBMs each year which plans are QHPs. For each QHP issuer, we estimate that it would take secretaries and administrative assistants 7 hours (for an annual burden of \$263.76 at a rate of \$37.68 per hour) to identify, on average, approximately 25 QHPs offered by a QHP issuer. This estimate will vary by QHP issuer, since each QHP issuer would identify a different number of QHPs, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 275 QHP issuers combined to be 1,925 hours or approximately \$72,534.

F. ICRs Regarding Medical Loss Ratio (§§ 158.103, 158.130, 158.240, 158.241)

We propose to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i). We propose that issuers that elect to provide temporary premium credits to consumers during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond must account for these credits as reductions to premium for the applicable months when reporting earned premium for the applicable MLR reporting year. We also propose to add a new § 158.240(g) to explicitly allow issuers to prepay a

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portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, we propose to amend § 158.241(a)(2) to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Finally, we propose to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS. We anticipate that implementing these provisions would require minor changes to the MLR Annual Reporting Form, but would not significantly increase 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. A revised collection of information seeking OMB approval for an additional 3 years is currently under review by OMB.

G. ICRs Regarding State Innovation Waivers (31 CFR 33.108, 45 CFR 155.1308, 31 CFR 33.120, 45 CFR 155.1320, 31 CFR 33.128 and 45 CFR 155.1328

In this proposed rule, the Departments propose to reference and incorporate the existing 2018 Guidance in full into the section 1332 waiver implementing regulations in order to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. This rule does not propose to alter any of the requirements related to state innovation waiver applications, compliance and monitoring, or evaluation in a way that would create any additional costs or burdens for states seeking waiver approval or those states with approved waiver plans. The Departments anticipate that implementing these provisions

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would not significantly change the associated burden. The burden related to this information collection (Review and Approval Process for Waivers for State Innovation (CMS-10383)) is currently under review by OMB.

H. ICRs Regarding Special Enrollment Period Verification (§ 155.420)

State Exchanges provide periodic reporting of Exchange enrollment data to CMS, including enrollments through SEPs by type, under OMB 0938-1119. We anticipate this PRA would cover the collection of this information. We will separately notice updates to this PRA package, if any, associated with this proposal.

I. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 11: Proposed Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB control number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$)	Total Cost (\$)
§ 155.220(c)(6)	0938-NEW	30	30	19	570	\$43,970	\$43,970
§ 155.221(b)(4)	0938-NEW	77	77	9	693	\$53,458	\$53,458
§ 155.221(b)(4) - Business Requirements Audit	0938-NEW	4	4	72	288	\$22,020	\$22,020
§ 155.221(b)(4) - Security and Privacy Audit	0938-NEW	14	14	122	1,708	\$130,594	\$130,594
156.295 & 184.50 (PBM Burden)	0938-NEW	40	40	2,175	87,013	\$6,527,571	\$6,527,571
156.295 & 184.50 (QHP Issuer Burden)	0938-NEW	275	275	7	1,925	\$72,534	\$72,534
Total		440	440		92,197	\$6,850,147	\$6,850,147

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 11.

J. 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.

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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 ICRs. 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–9914–P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due [INSERT DATE 60-DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

VI. 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.

VII. Regulatory Impact Analysis

A. Statement of Need

This rule proposes standards related to the risk adjustment program for the 2022 benefit year and beyond. Additionally, this rule proposes the premium adjustment percentage and associated parameters and FFE and SBE-FP user fees for the 2022 benefit year. It also includes proposed changes related to special enrollment periods; Navigator program standards; direct enrollment entities; and the administrative appeals process with respect to health insurance

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issuers and non-federal governmental group health plans; and the medical loss ratio program. It also proposes changes to the regulation to require the reporting of certain prescription drug information for QHPs or their PBM. In addition, it proposes to create a new direct enrollment option for State Exchanges and FFE states. In addition, relating to State Innovation Waivers, it proposes to reference and incorporate sections of the 2018 Guidance into the section 1332 waiver implementing regulations in order to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments.

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 one year).

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Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. A RIA must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and a “significant” regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of \$100 million or more in at least one year, and therefore, meets the definition of “significant rule” under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

The provisions in this proposed rule aim to ensure that consumers continue to have access to affordable coverage and health care, and that states have flexibility and control over their insurance markets. They would reduce regulatory burden, reduce administrative costs for issuers, web-brokers and direct enrollment entities, and states, ensure greater market stability, increase transparency and availability of QHP survey data, and increase transparency on the impact of PBMs on the cost of prescription drugs for QHPs. Through the reduction in financial uncertainty

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for issuers and increased affordability for consumers, these proposed provisions are expected to increase access to affordable health coverage.

Affected entities, such as Exchanges, issuers and FFE Classic Direct Enrollment and Enhanced Direct Enrollment partners, would incur costs to implement new special enrollment period requirements; State Exchanges would incur costs to implement and operationalize special enrollment period verification; and web-brokers and direct enrollment entities would incur costs to comply with operational readiness demonstration requirements. QHP issuers and PBMs would incur costs to implement and operationalize drug data reporting. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A-4, Table 12 depicts an accounting statement summarizing HHS'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 allowing consumers to have continued access to coverage and health care, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this proposed rule. The effects in Table 12 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 12 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers.

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We are proposing the risk adjustment user fee of \$0.25 PMPM for the 2022 benefit year to operate the risk adjustment program on behalf of states,²⁴⁶ which we estimate to cost approximately \$60 million in benefit year 2022. We expect risk adjustment user fee transfers from issuers to the federal government to remain steady at \$60 million, the same as those estimated for the 2021 benefit year.

For 2022, we are considering two additional proposals. First, we are proposing to reduce the FFE user fee rate from 3.0 percent of total premiums charged to 2.25 percent of total premiums charged, and we propose to reduce the SBE-FP user fee rate from 2.5 percent of total premiums charged to 1.75 percent of total premiums charged. For the 2023 benefit year, we propose FFE-DE and SBE-FP-DE user fee rate of 1.5 percent of total premiums charged. While our current budget estimates may change in the future, we believe that it is important to keep the user fee in all markets at the lowest level possible to cover the costs of the Exchanges to keep premiums low for consumers and issuers. We expect transfers from the issuers to federal government to be reduced by approximately \$270 million in 2022 and by approximately \$400 million in 2023 due to changes in user fee rates and state transitions; transitions from FFE or SBE-FP to State Exchange, SBE-FP, or FFE-DE are included in the reduction in user fee transfers from issuers to federal government.

²⁴⁶ 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.

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TABLE 12: Accounting Statement

Benefits:				
Qualitative:				
<ul style="list-style-type: none"> Continued access to coverage and health care due to new special enrollment periods. Greater market stability resulting from updates to the risk adjustment methodology. Strengthened program integrity related to the proposal to require Exchanges to conduct special enrollment period verification. Increased probability that consumers are able to maintain continuous coverage as a result of receiving MLR rebates sooner. Increased transparency on the impact of PBMs on the cost of prescription drugs for QHPs. Increased certainty for states regarding the application and ongoing approval process for section 1332 waiver applications, leading to increase in state innovation. 				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$ 7.02 million	2020	7 percent	2021-2025
	\$ 6.88 million	2020	3 percent	2021-2025
Quantitative:				
<ul style="list-style-type: none"> Costs incurred by web-brokers and direct enrollment entities to comply with requirements related to demonstration of operational readiness and compliance with applicable requirements; and by issuers and PBMs to implement and operationalize drug data reporting, as detailed in the Collection of Information Requirements section, estimated to be approximately \$14.5 million in 2021 and approximately \$3 million 2022 onwards. Reduction in potential costs for states submitting multi-year state flexibility requests estimated to be approximately \$22,000 over 3 years, starting with request submissions in 2021. Costs incurred by issuers of risk adjustment covered plans for audits, audits of issuers of reinsurance eligible plans, and audits of APTC, CSR, and user fee programs, estimated to be approximately \$2 million on average annually in 2021-2025. Costs incurred by State Exchanges to implement and operationalize special enrollment period verification, estimated to be one-time costs of approximately \$108 million incurred over 2021-23 and ongoing annual costs of approximately \$1.4 million in 2024 and 2025. Reduction in potential costs to Exchanges since they would not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be savings of \$113 million in 2022. Regulatory familiarization costs of approximately \$27,000 in 2020. 				
Qualitative:				
<ul style="list-style-type: none"> Increased costs due to increases in providing medical services (if health insurance enrollment increases). 				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	- \$280.5 million	2020	7 percent	2021-2025
	- \$287.8 million	2020	3 percent	2021-2025
Quantitative:				
<ul style="list-style-type: none"> Reduction in transfers from the issuers to federal government by approximately \$270 million in 2022 and approximately \$400 million 2023 onwards due to changes in user fee rates and state transitions, including the proposed availability of FFE-DE and SBE-FP DE options to issuers and states beginning with the 2023 benefit year. Transfers to the federal government from FFE states that are transitioning to, or intend to transition to, being State Exchanges, for conducting special enrollment verification, estimated to be approximately \$1.75 million annually in 2024 and 2025. 				

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,

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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 12 or 13. Table 13 summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2022 through 2026, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to significantly alter CBO’s estimates of the budget impact of the premium stabilization programs that are described in Table 13.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. These analyses exclude any potential effects from states electing to use the FFE-DE or SBE-FP-DE models. 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 2021 Payment Notice for the impacts associated with the APTCs, the premium stabilization programs, and FFE user fee requirements.

TABLE 13: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2022-2026, in billions of dollars²⁴⁷

Year	2022	2023	2024	2025	2026	2022-2026
Risk Adjustment and Reinsurance Program Payments	6	6	7	7	8	34
Risk Adjustment and Reinsurance Program Collections	6	6	7	7	8	34

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.

Source: Congressional Budget Office. *Net Federal Subsidies Associated With Health Insurance Coverage, 2020 to 2030*. March 6, 2020. Available at <https://www.cbo.gov/system/files/2020-03/51298-2020-03-healthinsurance.pdf>.

1. Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets (§ 147.104)

²⁴⁷ Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

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The proposed revision to § 147.104(b)(4)(ii) would allow an individual or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to use the date the individual knew, or reasonably should have known, of the occurrence of the triggering event as the date of the triggering event for a special enrollment period to enroll in individual market coverage through or outside of an Exchange. This would enable consumers to maintain continued access to coverage and health care.

2. CMS Enforcement in Group and Individual Markets (Part 150)

We propose to remove the requirement to file submissions to the Departmental Appeals Board in triplicate and instead require electronic filing. Based on our experience, such filings are infrequent, and this proposed change would not have a significant impact. An entity filing a submission would experience a small reduction in costs related to printing and mailing the submission.

3. Risk Adjustment (Part 153)

The risk adjustment program is a permanent program created by section 1343 of the 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 2022 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. For the 2022 benefit year, we have

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used the same methodology that we finalized in the 2020 Payment Notice to estimate our administrative expenses to operate the program. Risk adjustment user fee costs for the 2022 benefit year are expected to remain steady from the prior 2021 benefit year estimates of approximately \$60 million. We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states and the District of Columbia for 2022 will be approximately \$60 million, and the risk adjustment user fee will be \$0.25 PMPM. Because of the increase in costs estimated for the 2022 benefit year, we expect the final risk adjustment user fee for the 2022 benefit year to neither increase or decrease transfers from issuers of risk adjustment covered plans to the federal government.

Additionally, for the risk adjustment factors, we proposed to recalibrate the HHS risk adjustment models for the 2022 benefit year by using the 2016, 2017 and 2018 enrollee-level EDGE data, the same data used for the 2021 benefit year. We adopted an approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk adjustment models for the 2021 benefit year and beyond. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2021 benefit year to the 2022 benefit year. We also propose, for the 2022 benefit year, to make model specification changes to the risk adjustment models to add a two-stage specification and interacted HCC counts factors to the adult and child risk adjustment models, to revise the enrollment duration factors for the adults models and to continue a pricing adjustment for Hepatitis C drugs for all three models (adult, child and infant). Overall, these proposed changes would make limited changes to the number and type of risk adjustment model factors; therefore, we do not expect

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these changes to impact issuer burden beyond the current burden for the risk adjustment program.

We propose that issuers that choose to offer premium credits to consumers during a declared PHE, when HHS permits such credits, must report the adjusted plan premium amount, taking into account the credits provided to consumers as a reduction to premiums for the applicable months for risk adjustment data submissions for the 2021 benefit year and beyond. We do not believe that the clarifications regarding risk adjustment reporting in this proposal would impose additional administrative burden on health insurance issuers beyond the effort already required to submit data to HHS for the purposes of operating risk adjustment, as previously estimated in the interim final rule on COVID-19 (85 FR 54820).

In the 2021 Payment Notice, HHS finalized the risk adjustment state payment transfer formula under the HHS risk adjustment methodology for the 2021 benefit year, and reaffirmed that HHS will continue to operate the risk adjustment program in a budget neutral manner. We propose to maintain the same methodology and continue to operate risk adjustment in a budget neutral manner for the 2022 benefit year and beyond, unless changed through notice with comment rulemaking. Therefore, there is no net aggregate financial impact on health insurance issuers or the federal government as a result of the risk adjustment provisions with respect to the premium credit related proposals. However, while risk adjustment transfers are net neutral in aggregate, we recognize that individual issuers may be financially impacted by reduced transfers (either lower risk adjustment payments or lower risk adjustment charges) if any issuer in the issuer's state market risk pool provides premium credits to enrollees. The extent of this impact will vary based on the number of issuers in a state market risk pool that elect to provide the

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temporary premium credits during a declared PHE, the amount of these premium credits provided, as well as the market share of the issuers that provide these premium credits.

We do not believe that the impact of this proposal will vary from what was previously estimated in the interim final rule on COVID-19 (85 FR 54820). Similar to our analysis of regulatory impacts in the interim final rule on COVID-19, we recognize the potential for financial impacts for individual issuers as a result of the clarifications in this proposal. We believe that if HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur which could also financially impact individual issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-than-average risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool.

For all of these reasons, we believe that requiring issuers that offer temporary premium credits for 2021 and future benefit years' coverage to accurately report to the EDGE server the adjusted, lower premium amounts actually charged to enrollees is most consistent with existing risk adjustment program requirements. We also believe this requirement would mitigate the distortions that would occur if issuers that offer these temporary premium credits did not report

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the actual amounts charged to enrollees, while avoiding additional financial burden on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts.

Beginning for the 2023 benefit year, we are proposing to allow state regulators to request a reduction in the calculation of risk adjustment transfers under the state payment transfer formula for up to 3 years. HHS would reserve the right to require states with approved multi-year reduction requests to submit supplemental evidence in any subsequent year of the request after its initial approval, in the timeframe, form, and manner specified by HHS, and HHS would also reserve the right to terminate or modify an approved multi-year request prior to its natural expiration. We are also proposing to permit states with approved multi-year requests to withdraw their respective request before its natural expiration by notifying HHS of its requested withdrawal. HHS would require states to inform impacted issuers of any termination, modification, or withdrawal of an approved multi-year reduction request.

Allowing multi-year state flexibility requests would lead to a reduction in burden associated with this requirement for states who elect to submit such requests. In the 2019 Payment Notice, we estimated that it would take a business operations specialist 32 hours to prepare an annual state flexibility request and 16 hours for a senior manager to review the request and transmit it electronically to HHS, for a total burden of 48 hours. The total burden over 3 years would be 144 hours. For states submitting multi-year requests, we estimate that it would take a business operations specialist 64 hours (at a rate of \$77.14 per hour) to prepare the request and 32 hours for a senior manager (at a rate of \$118.30 per hour) to review the request and transmit it electronically to HHS. We estimate that each state seeking a multi-year reduction request would incur a total burden of 96 hours at a cost of approximately \$8,723 to comply with this reporting requirement (64 hours for the business operations specialist and 32 hours for the

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senior manager). If HHS requests supplemental evidence from a state to support the continued application of its request, we estimate that the state would incur a cost of approximately \$1,090 (8 hours for the business operations specialist at an hourly wage of \$77.14 and 4 hour for the senior manager at an hourly wage of \$118.30). We estimate that a state withdrawal of a previously submitted request would impose minimal additional cost of approximately \$118 on the state associated with a senior official from the State Department of Insurance submitting a withdrawal request to HHS and informing impacted issuers of the withdrawal (equivalent to 1 hour for a senior manager at an hourly wage rate of \$118.30). Each state that submits a multi-year request would experience a cost reduction of approximately \$4,361 over a period of 3 years (our estimate of a state's cost savings would be reduced to approximately \$3,271 if HHS requests supplemental evidence from the state one time over a period of 3 years). Although we are unable to precisely estimate the number of states that would make these requests, we expect that no more than 5 states would make these requests annually.²⁴⁸ For 5 states, the total reduction in burden would be 240 hours with a cost reduction of approximately \$21,806 (less if HHS requests supplemental evidence). We seek comment on this estimated burden reduction.

We are proposing to provide more clarity regarding audits and compliance reviews of issuers of risk adjustment covered plans through proposed amendments to § 153.620(c). Issuers being audited under the risk adjustment program would be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. We are also proposing to codify our authority to recoup risk adjustment (including high-cost risk pool)

²⁴⁸ To date, only one state (Alabama) has pursued this flexibility.

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payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with risk adjustment program (including high-cost risk pool) audits would take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer would be approximately \$14,356. While the number of issuers participating in the risk adjustment program varies per benefit year, (for example, there were 751 issuers participating in the risk adjustment program for the 2016 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30-60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited would be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

We are proposing to increase the materiality threshold for EDGE discrepancies, beginning in the 2020 benefit year, so that HHS may only take action if the amount in dispute is equal to or exceeds \$100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less. As a result of this proposal, some discrepant issuers would no longer be charged for their EDGE data error. In addition, issuers in the same state market risk pool as the discrepant issuer would not receive positive adjustments to their risk adjustment transfers. This is because HHS's process for addressing material EDGE data discrepancies is to recalculate the dollar value of any difference in risk adjustment transfers, charge the discrepant issuer for the difference, and compensate the issuers who were harmed by the amount of that calculation in order to balance the market. Based on analysis of discrepancies from prior years' data, payments to these issuers are occasionally as low as \$1.00 and typically

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represent a fraction of one percent of the issuer's overall transfers in the state market risk pool for the applicable benefit year. We anticipate that the proposal would have a minimal impact on regulatory burden. There might be a slight reduction in administrative burden to some issuers who currently report, and receive adjustments for, EDGE discrepancies that are less than a fraction of total state market risk pool transfers.

4. Audits of Reinsurance-Eligible Plans (§ 153.410(d))

We are proposing to provide more clarity regarding audits and compliance reviews of reinsurance-eligible plans through proposed amendments to § 153.410(d). Issuers being audited under the reinsurance program would be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. We are also proposing to codify our authority to recoup reinsurance payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with reinsurance program audits would take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer would be approximately \$14,356. There were 557 issuers participating in the reinsurance program for the 2015 and 496 issuers participating in the reinsurance program audits for the 2016 benefit year; however, HHS would only audit a small percentage of these issuers, roughly 30-60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited would be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

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5. Risk Adjustment Data Validation (§ 153.630(g))

In this proposed rule, we are proposing to codify two previously-established exemptions from HHS-RADV under § 153.630(g). These exemptions apply when the issuer only has small group carryover coverage for the applicable benefit year or when an issuer is in the sole issuer in the state market risk pool for the applicable benefit year (and did not participate in another risk pool with other issuers for that benefit year). Under these exemptions, these issuers are not be required to complete HHS-RADV for the given benefit year, and therefore, they would have a decreased administrative burden. However, given that these exemptions are limited to issuers exiting all markets in a state and issuers who are sole issuers in all markets in a state, we estimate that 13 issuers would be exempt from HHS-RADV for a given benefit year under these exemptions. We further note that these exemptions are not establishing new exemptions; instead, the proposed amendments to § 153.630(g) would simply further codify existing policies.

We also propose to change the HHS-RADV collections timeline from the timeline finalized in the 2020 Payment Notice in response to stakeholder feedback. Under the proposed timeline, we would implement the collection of HHS-RADV charges and disbursement of payments in the calendar year in which HHS-RADV results are released. We do not believe this proposal would change the administrative burden previously estimated as we understand that the majority of states and issuers follow a timeline that aligns more closely with the one proposed in this rulemaking and few pursued the flexibility provided under the timeline finalized in the 2020 Payment Notice.

6. Direct Enrollment (§§ 155.205, 155.220, and 155.221)

a. Enhanced Direct Enrollment Website Translations

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We propose to allow QHP issuers and web-brokers participating in the FFE EDE program additional time to come into compliance with the website content translation requirements in §§ 155.205(c)(2)(iv)(B) and (C) for the website content added to their websites to participate in the FFE EDE program. Specifically, we propose for a QHP issuer or web-broker participating in the FFE EDE program to have 12 months from the date the QHP issuer or web-broker begins operating its EDE website in the relevant state to translate website content added to their websites to participate in the FFE EDE program according to the requirements in §§ 155.205(c)(2)(iv)(B) and (C). This would not absolve QHP issuers and web-brokers from translating website content subject to the requirements in §§ 155.205(c)(2)(iv)(B) and (C)²⁴⁹ that is unrelated to their participation in the FFE EDE program. For example, a QHP issuer's or web-broker's implementation of the Exchange eligibility application on its website for purposes of participation in the FFE EDE program would be considered content added to its website to participate in the FFE EDE program and would be afforded the additional time for translation into applicable languages. However, QHP issuer website content subject to the § 155.205(c)(2)(iv)(C) requirements, such as Summaries of Benefits and Coverage or provider directories, would not be afforded additional time for translation into applicable languages. Similarly, website content related to a web-broker's participation in Classic DE that is subject to the § 155.205(c)(2)(iv)(C) requirements, such as plan selection pages displaying QHPs, would not be afforded additional time for translation into applicable languages beyond the one year after the web-broker has been registered with the Exchange. We believe that providing QHP issuers and web-brokers participating in the EDE program with additional time to come into

²⁴⁹ See "Guidance and Population Data for Exchange, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250," March 30, 2016. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf>.

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compliance with the website content translation requirement for the website content added to their websites to participate in the FFE EDE program would be warranted given the significant resources associated with obtaining approval to participate in the FFE EDE program generally. Given the significant cost of third-party EDE audit requirements, providing additional time to QHP issuers and web-brokers participating in the FFE EDE program to complete website translations of website content added to their websites to participate in the FFE EDE program would provide an incentive for such entities to enter markets where there is a significant number of LEP individuals, while also ensuring that website content would be accessible for individuals with LEP within a reasonable period of time. We are of the view that this flexibility would enable interested QHP issuers and web-brokers participating in the EDE program to test the market before incurring additional translation costs, which would enable smaller QHP issuers and web-broker entities to compete more effectively. Therefore, affording this additional time for translation of EDE-specific website content should reduce the burden on QHP issuers and web-brokers, at least for their first year of operations as an EDE entity in a state where the §§ 155.205(c)(2)(iv)(B) and (C) requirements apply.

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

We propose to permit, but not require, assisters in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided the non-Exchange website meets certain conditions and to the extent permitted by state law. Web-brokers have developed innovative tools to support consumers shopping for QHP coverage through their non-Exchange websites for both Classic DE and EDE that assisters and the consumers they assist may find helpful when shopping for and enrolling in QHPs offered through Exchanges. In addition, some web-brokers have expressed interest in leveraging

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assisters' expertise in navigating more complex enrollment cases to provide additional support to the consumers they serve. At the same time, assisters have expressed a desire to obtain access to an improved consumer experience by leveraging innovative and unique consumer assistance tools and display features many web-brokers have developed for Classic DE and EDE.

Additionally, some assisters have expressed a desire to have access to real-time information on the status of submitted applications and enrollments that is available through EDE to more effectively assist consumers. Although we are not proposing to require web-brokers develop assister portals for their non-Exchange websites, we recognize that some web-brokers may consider developing such portals to enable assisters to gain easy access to real-time information for each of the consumers they assist using the web-broker's non-Exchange website, similar to portals some web-brokers have already developed for affiliated agents and brokers who have entered into arrangements to access the web-broker's non-Exchange website. If the web-broker's non-Exchange website meets applicable requirements, we want to encourage this type of innovation to improve the experience for assisters and the consumers they assist with shopping for and enrolling in QHPs offered through an Exchange.

We are proposing several amendments to § 155.220 to capture new flexibility for assisters in FFE and SBE-FP states to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent permitted by state law. This proposed flexibility would extend to both Classic DE and EDE websites that web-brokers may offer to assist consumers in FFE and SBE-FP states. We propose new § 155.220(c)(3)(iii)(A) to require web-broker websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), for such websites to be eligible for use by assisters when otherwise

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permitted under state law. We note that web-brokers may obtain all QHP information they would be required to display in FFEs and SBE-FPs for assisters to be permitted to use their websites by integrating with the FFEs' Marketplace API. For FFEs and SBE-FPs, we are considering adoption of an optional annual certification process for web-brokers that would be integrated into the existing annual web-broker registration process, or could occur during another time of year, during which a web-broker could be certified by the Exchange by attesting to its compliance with the requirements proposed in § 155.220(c)(3)(iii)(A). We propose to capture this optional annual certification process at new proposed § 155.220(c)(3)(iii)(B). We are also considering maintaining a public list of certified web-brokers in FFEs or SBE-FPs, so that assisters would be able to more easily identify web-broker websites they might seek to use in FFEs and SBE-FPs, when such arrangements are permitted under state law. The proposed amendments to § 155.220(c)(3)(iii)(A) would also provide that if a web-broker website does not facilitate enrollment in all QHPs it would be required to identify to consumers the QHPs, if any, for which the web-broker website does not facilitate enrollment by prominently displaying a standardized disclaimer provided by the Exchange, in a form and manner specified by the Exchange, stating that the consumer can enroll in such QHPs through the Exchange website, and display a link to the Exchange website. We anticipate issuing further guidance on the form and manner in which the disclaimer should be displayed so that it would be clearly associated with any QHPs for which the web-broker does not facilitate enrollment. We are considering whether the disclaimer or a link to the disclaimer should replace the link or other mechanism the web-broker would otherwise display to allow a consumer to proceed with selecting and enrolling in a QHP, or whether the disclaimer should be displayed in some other fashion. This proposal would not require a web-broker to modify its website unless it wishes for assisters to be able to use its

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website. If a web-broker chooses to leverage this flexibility, there may or may not be an associated burden. For example, some web-brokers are already displaying all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1), and may already facilitate enrollment in all QHPs. For such web-brokers, there would be no website modifications required to add QHP information or to display a disclaimer and therefore assisters would be permitted to use those web-broker websites if this policy were finalized with no actions required by the web-broker. In other cases, web-brokers might need to update their websites to add QHP information consistent with the requirements of § 155.205(b)(1), or might need to add a disclaimer if the web-broker does not facilitate enrollment in all QHPs to identify to consumers the QHPs for which the web-broker website does not facilitate enrollment. In general, we expect this proposal would add little to no new burden for existing web-brokers, because the web-brokers most likely to take advantage of this flexibility are probably those that already have websites that meet the requirements proposed at new § 155.220(c)(3)(iii) or can meet those requirements with minimal updates to their websites.

c. QHP Information Display on Web-broker Websites

We propose to provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for QHPs in certain circumstances. In new proposed § 155.220(n), we propose to establish an exception to the web-broker display requirements captured at § 155.220(c)(3)(i)(A) and (c)(3)(i)(D). At new proposed § 155.220(n), we propose certain flexibilities regarding display of QHP information if a web-broker's non-Exchange website does not support enrollment in a QHP. This situation could occur if the web-broker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances,

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we propose that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, web-brokers would be required to display the following limited, minimum information for such QHPs: issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information. To take advantage of this new proposed exception, we also propose that the web-broker's non-Exchange website would be required to identify to consumers the QHPs, if any, for which the web-broker's website does not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange Website, and includes a link to the Exchange Website. To more closely align the plan detail disclaimer text²⁵⁰ with the intent of this proposal, we would issue further guidance slightly revising the text of the disclaimer. For example, the current disclaimer text states, in relevant part, the web-broker "isn't able to display all required plan information about this Qualified Health Plan at this time." We would modify that text so that it states, in relevant part, the web-broker "doesn't display all plan information about, and does not facilitate enrollment in, this Qualified Health Plan at this time." We believe this proposal strikes an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. It also would minimize burdens for web-brokers by not requiring them to build functionality and processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for

²⁵⁰ See Section 5.3.2 of the "Federally-Facilitated Exchanges (FfEs) and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual." Available at https://www.regtap.info/uploads/library/ENR_FFEFFSHOPENrollmentManual2020_5CR_090220.pdf.

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which they do not have an appointment to sell. We believe the burden associated with this proposal would be very limited as it would largely align with our historical enforcement approach and guidance. Web-brokers that are not displaying all the QHP information required under § 155.205(b)(1) are already displaying the plan detail disclaimer, a link to the Exchange website, and the following limited details: issuer marketing name, plan marketing name, plan type, and metal level. The one new requirement that this proposal would impose is the display of premium and cost-sharing information for all QHPs. However, premium and cost-sharing information is and has been available through the Exchange public use files and the Marketplace API for some time now, and web-brokers are familiar with those data sources to populate their websites with other QHP information. Furthermore, premium and cost-sharing information is data web-brokers already incorporate for at least some QHPs displayed on their websites. Incorporating premium and cost-sharing information for all QHPs displayed on their websites would require a minimal level of effort.

d. Web-broker and Direct Enrollment Entity Operational Readiness Review Requirements

At § 155.220(c)(6), we propose a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's website being used to complete an Exchange eligibility application or a QHP selection. As reflected in proposed § 155.220(c)(6)(i) through (iv), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation might include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and

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privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes might include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers will have to maintain and provide access to testing environments that reflect their prospective or actual production environments. We are proposing these amendments to codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.²⁵¹ Some of these requirements, such as the collection of operational data, have effectively existed for many years, and so they would impose little to no new burden. The collection of security and privacy assessment documentation would be a new requirement, although historically the web-broker agreement has required web-brokers to attest to the implementation and assessment of privacy and security controls. As a result, web-brokers should have historically completed any technical implementation of the controls and should be familiar with assessment of those controls. Completion of enrollment testing would also be a new requirement, but use of the direct enrollment pathway inherently requires a web-broker's platform to be capable of processing enrollments. Therefore, the burden of testing that functionality would be very limited. Website reviews have been conducted historically and are performed by HHS, so there would be no burden to web-brokers associated with the completion of those reviews. The burden related to

²⁵¹ See, for example, "Updated Web-broker Direct Enrollment Program Participation Minimum Requirements," May 21, 2020. Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf>.

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these proposed requirements is discussed in the Collection of Information Requirements section above.

We propose to revise § 155.221(b)(4) to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new proposed § 155.220(c)(6), we are proposing these amendments to codify in § 155.221(b)(4) more details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We note that these proposed requirements are in addition to the operational readiness requirements at new proposed § 155.220(c)(6) for web-brokers, although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in direct enrollment programs and the source and type of documentation.

In paragraph (b)(4), we propose to continue to require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We add new proposed paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit or complete, in the form and manner specified by HHS, a number of artifacts of documentation or various testing or training processes. The documentation may include business audit documentation including: notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The

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required documentation may also include security and privacy audit documentation including: interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results.

Submission of agreements between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program may also be required.

Required testing may include eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in direct enrollment programs. We expect minimal new burden associated with this proposal as these requirements have historically been established through agreements EDE entities have executed with HHS, and therefore entities have completed these tasks in the past to be able to use the EDE pathway. The burden related to these proposed requirements is discussed in the Collection of Information Requirements section above.

e. Direct Enrollment Entity Plan Display Requirements

We also propose to revise § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. This proposal would constitute a revision of a policy adopted in 2019. We anticipate this policy would provide increased flexibility and believe many direct enrollment entity websites are already designed in a manner largely consistent with this proposal, and therefore the burden associated with it would be minimal.

f. New Exchange Direct Enrollment (DE) options

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We also propose to add § 155.221(j) establish a new Exchange direct enrollment (DE) option, beginning with PY 2022, in which states could use direct enrollment technology to transition to private sector-focused enrollment pathways operated by QHP issuers, web brokers, and agents and brokers instead of a centralized front-facing eligibility and enrollment website operated by the Exchange. State Exchanges, as well as SBE-FP, and FFE states could elect to implement the DE option. The impact of the new Exchange DE option will depend on the specific Exchange model and the number of states that take advantage of the new option. The FFEs' current direct enrollment program (classic and EDE) generally reduce operational costs to the federal government while alleviating certain burdens on consumers.

This proposal may have varied impacts on consumers, and we are interested in public comments that would better help us to understand how the DE option, and an increase in the number of potential websites maintained by brokers through which consumers could shop for QHP coverage, might impact consumers and consumer behavior with respect to QHP enrollment. We also note that any operational cost increases or savings for implementation of the DE option could, in turn, affect an SBE's user fee and consumer premium costs.

Under the FFE-DE and SBE-FP-DE, CMS would be providing back end eligibility services, notice and tax form generation, the processing of data matching and special enrollment verification issues, eligibility appeals, casework, advanced customer service, enrollment reconciliation, IRS reporting, and an alternate / backup consumer-facing process (as we do today). In addition, the HealthCare.gov website would continue to provide standardized comparative information for QHPs offered on the Exchange.

At this time, we do not anticipate that any of the 15 current SBEs would implement the DE option, as they have to date not implemented the same direct enrollment interfaces with web

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brokers or other direct enrollment entities as the FFE. However, current SBEs that elect to apply for approval to implement the DE option would be responsible for meeting certain requirements for approval, in particular revising their Exchange Blueprint (Blueprint) under new proposed § 155.221(j)(1). We believe that any costs of revising the Blueprint would be nominal, as this process involves logging electronically into a CMS web interface that serves as the repository for all states' Blueprints to input additional information on updated processes and controls to manage the new DE program. However, we seek comment on the burden associated with this activity and note that the Blueprint is currently approved under the PRA under OMB Control Number 0938-1172.

For states seeking to transition to a SBE for future plan years in order to utilize the new Exchange DE option, we anticipate that start-up costs would be similar to those associated with recent transitions to the SBE model, including any costs associated with the completion of the Blueprint. SBEs would complete the Blueprint in the same manner and would be required to meet all required minimum functions of an Exchange. In terms of implementation costs, these states could realize savings by virtue of not having to build the consumer-facing website to handle the consumer traffic that it would handle if it were the single point of enrollment, instead relying on direct enrollment entities to provide the majority or all of the enrollment functionality. However, those may be relatively lower costs than the costs associated with building the back-end Exchange eligibility platform to complete eligibility determinations, along with the applicable connections required to the Federal Data Services Hub for performing eligibility verifications, as well as connections to the respective state Medicaid agency for coordinating Medicaid and CHIP eligibility determinations. Based on recent state transitions to the SBE model, the design, development, and implementation costs for an Exchange depend on a number

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of factors. Recent design, development, and implementation costs have ranged from \$4 million for a smaller state, to almost \$24 million for a larger state. As no SBE to date has implemented direct enrollment, however, we are not able to provide accurate cost estimates in this regard. States may also be able to use existing federal DE partners who are fully compliant with federal operational requirements to provide administrative savings. Any operational cost increases or savings could, in turn, affect an SBE's user fee and premium costs.

We do anticipate that an SBE electing the Exchange DE option would have increased operational costs for monitoring and oversight of the DE entities, as well as for maintaining and managing the individual interfaces and transactions with each DE entity. However, any savings achieved through a decrease in call center volume or other consumer supports due to DE partners assisting consumers with enrollment would offset any increased operational supports. Any operational savings could, in turn, affect an SBE's user fee.

We also anticipate that the DE option could have impacts on web-brokers and issuers. With respect to web brokers, costs may be incurred if there are new entrants to the DE market or if existing DE participants expand into new markets. We presume that web brokers will rationally only enter the market or expand into new markets if the benefits exceed the costs. Web brokers may enter into fee-based arrangements with issuers, or possibly new economic or legal arrangements with states, that help to offset the costs of the DE services provided. Web brokers may also assume costs associated with the optional certification process. Issuers will be impacted by adjustments in user fees, and may have an incentive to promote direct enrollment if user fees are lower under the DE option, and those savings exceed the new costs of arrangements with web brokers. Issuers may also be impacted if the DE option leads to shifts in consumer

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enrollment patterns, such as movement from a QHP offered by one issuer to a QHP offered by another issuer.

We also do not anticipate that HHS will have any increased costs associated with monitoring and oversight of the SBE-DEs. We note that changes in premiums may have downstream impacts on federal payments of PTCs.

We seek comment on this proposal, including any additional consumer, state and SBE, HHS, issuer, web-broker, or other costs, benefits or transfers that should be considered. We also seek data and information that would help us to quantify the potential impacts associated with this proposal.

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

As discussed previously in the preamble, as for benefit years 2020 and 2021, we will not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4) for benefit year 2022, and we propose to amend § 155.320(d)(4) to reflect that the requirement will not be applied in plan years 2021 and 2022. HHS's experience conducting random sampling revealed that employer response rates to HHS's request for information were low. The manual verification process described in paragraph (d)(4)(i) requires significant resources and government funds, and the value of the results ultimately does not appear to outweigh the costs of conducting the work because only a small percentage of sample enrollees have been determined by HHS to have received APTC/CSRs inappropriately. We estimate the annual costs to conduct sampling on a statistically significant sample size of approximately 1 million cases to be approximately \$6 million to \$8 million for the Exchanges using the Federal platform and State Exchanges that operate their own eligibility and enrollment platforms. This

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estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. We estimate that the total annual cost for the Exchanges using the Federal platform and the 15 State Exchanges operating their own eligibility and enrollment platform in 2022 would be \$113 million. Relieving Exchanges of the requirement to conduct sampling for benefit year 2022 would therefore result in total savings of approximately \$113 million. We seek comment on this estimate.

8. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for APTC

We propose to add a new paragraph at § 155.420(a)(4)(ii)(C) to allow Exchange enrollees and their dependents who become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of a lower metal level. We anticipate that this proposal would help impacted enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of losing a potentially significant amount of financial assistance to help them purchase coverage. For example, an enrollee impacted by an increase to his or her monthly premium payment could change to a bronze-level plan, or to catastrophic coverage if they are otherwise eligible. Relatedly, this proposal may benefit the individual market risk pool by encouraging healthy individuals to maintain continuous coverage. Currently, an enrollee who loses APTC eligibility has only two choices: paying the full premium or terminating his or her coverage. Healthy individuals who lose APTC may be more likely to terminate coverage due to increased premium liability, while enrollees who have one or more medical conditions will be incentivized to maintain coverage in spite of the additional expense. This proposal would serve to facilitate continuous coverage of healthy individuals by giving them the ability to enroll in a new plan with a lower premium, thereby supporting a healthier risk pool.

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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, as discussed earlier in the preamble, we seek comment on whether there are concerns about adverse selection risk with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether this risk would be significantly lower if we only permit an enrollee to change to a plan one metal level lower than their current QHP. We also request comment from issuers on whether there are concerns about impacts such as experiencing a decrease in premium receipts from enrollees who opt to change to a lower-cost plan, or whether they view adverse selection as a possibility. As discussed in more detail earlier in the preamble, we also acknowledge that enrollees may lose APTC eligibility and qualify for a special enrollment period due to their APTC loss for a reason other than a change in household income or tax family size. We seek comment on whether stakeholders have concerns with this possibility, as well as on how HHS can help ensure that enrollees who lose APTC because of failure to provide information to the Exchange to confirm their APTC eligibility can understand and take action on steps needed to do so, even if they also have the flexibility to change to a plan of a lower metal level.

We recognize, as further discussed in preamble, that changing to a new QHP mid-plan year may cause enrollees to incur additional out of pocket costs, as a new QHP selection typically resets the enrollee's deductible and other accumulators. We believe that Exchange enrollees who lose APTC eligibility are best able to weigh the trade-off between reset accumulators and maintaining an affordable monthly premium, and losing coverage altogether.

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Enrollees who qualify to make a new plan selection for an applicable special enrollment period already must consider this question. However, we request comment on whether this proposal would increase the risk that consumers will change plans without taking into account potential disadvantages, and on strategies to help mitigate this risk, such as consumer education.

Additionally, this proposal would impose a cost to Exchanges that have implemented plan category limitations, because it would require the use of financial and staff or contractor resources to make a change to application and plan selection system logic to permit applicable enrollees and dependents to change to a lower metal level plan after having previously restricted them to plans of their current metal level. Therefore, we solicit comments on the extent to which Exchanges would experience burden due to this proposed change, and we also seek comment on whether we should exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether to help to mitigate this burden, or whether such a change would significantly increase risk for adverse selection.

Finally, 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 – untimely notice of triggering event

We anticipate that the proposed amendments related to qualified individuals who do not receive timely notice of a triggering event and otherwise are reasonably unaware that a triggering event occurred would provide certain consumers a pathway to maintain continuous coverage, which would have an overall positive impact on the risk pool and would benefit consumers. Consumers would benefit from being able to maintain continued access to coverage and health

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care. We recognize the possibility of some minor adverse selection risk given that consumers with known health issues may be more likely to request a retroactive effective date than healthy consumers. However, we expect this risk to be very limited as the proposal only permits individuals to request a retroactive effective date if they did not receive timely notice of a triggering event, and we do not expect this to happen very often.

We expect that Exchanges and Direct Enrollment partners might incur minor costs to update consumer messaging and processes to administer this proposal. State Exchanges that currently do not have this policy and issuers offering off-Exchange plans would incur minor costs to implement this proposal. We seek comment on this proposal, including any costs, benefits or burdens associated with this proposal.

c. Cessation of employer contributions to COBRA as special enrollment period trigger

We anticipate that the proposed amendments regarding special enrollment period eligibility for qualified individuals whose employers completely cease payment of their portion of COBRA continuation coverage premiums would provide clarity regarding a policy that has been operationalized on HealthCare.gov. We believe that these amendments would benefit direct enrollment partners and employers by providing clarity regarding special enrollment period eligibility. In addition, consumers who would have otherwise lost coverage due to an increase in the cost of their COBRA continuation coverage would benefit from continuity of coverage and access to healthcare.

Because this special enrollment period has already been available to individuals enrolling in a QHP on HealthCare.gov, we do not anticipate that these amendments would have any negative impact on the risk pool, nor would they increase costs for direct enrollment partners or HealthCare.gov. However, we do anticipate that State Exchanges that do not have this policy, as

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well as issuers who operate off-Exchange plans, would incur costs to implement this proposal. We seek comment on this proposal, including any associated costs, benefits or burdens.

d. Special enrollment period verification (§ 155.420)

We do not anticipate that revisions to § 155.420 would impose regulatory burden or costs on the Exchanges using the federal platform. We anticipate that this proposal would have a positive impact on program integrity by verifying eligibility for special enrollment periods. Increasing program integrity through this proposal could contribute to keeping premiums low and therefore, protect taxpayer dollars. However, FFE, SBE-FPs, and most State Exchanges already conduct special enrollment period verification in accordance with this proposal, so premium impact would likely be very minimal.

We anticipate this proposal would moderately increase regulatory burden on existing State Exchanges, along with FFE and SBE-FP states currently transitioning to establishing State Exchanges, that do not currently conduct special enrollment period verification for at least 75 percent of enrollments for newly enrolling consumers enrolling through special enrollment periods. A majority of State Exchanges currently conduct SEP verification for the same SEP types for which the FFEs currently conduct SEP verifications, with some State Exchanges conducting SEP verifications for additional SEP types, while 4 State Exchanges currently conduct SEP verifications for only one type of SEP. Those 4 State Exchanges include those in the District of Columbia, Maryland, Rhode Island, and Vermont. State Exchanges bear the full cost of the SEP verification activities they conduct. All the State Exchanges that currently conduct SEP verifications in the same manner as the FFEs do are verifying 75 percent or more of their respective SEP enrollments. This includes the State Exchanges with the highest SEP enrollment volume, such as the California and New York Exchanges. For the 4 State Exchanges

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that conduct SEP verifications for only one type of SEP, that SEP type consistently represents about 60 percent of all SEP enrollments across each of these four State Exchanges.

Based on the implementation of pre-enrollment special enrollment period verification in the Exchanges using the federal platform, we estimate that the overall one-time cost of implementing pre- or post-enrollment SEP verification by an Exchange would be approximately \$12 million. Therefore, we estimate that the total cost for the 4 existing State Exchanges that currently do not conduct special enrollment period verification for at least 75 percent of enrollments for newly enrolling consumers enrolling through special enrollment periods would be \$48 million in order to comply with this new requirement for PY 2024. Additionally, there would be costs for at least 1 FFE state and 4 SBE-FP states that are transitioning to, or have notified us that they intend to transition to, establishing State Exchanges on or after the 2021 plan year to implement this new requirement. We estimate that total implementation costs for these 5 states would be \$60 million. Including both categories of State Exchanges, total costs for State Exchanges to implement this new requirement are estimated to be \$108 million. We assume these costs will be incurred in the years 2021- 2023.

There also would be an increase in ongoing costs for 5 existing State Exchanges due to an increase in the number of special enrollment period enrollments for which they must conduct verification. We estimate that the total increase in ongoing costs for these 5 existing State Exchanges to comply with this requirement would be \$2.8 million for 2024 and 2025. We estimate that the Exchanges using the federal platform would not incur any increase in costs to comply with this requirement. In addition, the 1 FFE state and 4 SBE-FP states that are transitioning to, or have informed us that they intend to transition to, establishing State Exchanges, would incur costs to comply with this requirement instead of the FFEs, estimated to

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be \$3.5 million for 2024 and 2025, which would result in a transfer from the State Exchanges to the FFEs. We do not anticipate this proposal would increase regulatory burden or costs on issuers.

9. FFE and SBE-FP User Fees (§ 156.50)

We are proposing a lower FFE user fee rate of 2.25 percent for the 2022 benefit year, which is lower than the 3.0 percent FFE user fee rate finalized for 2021 benefit year. We also propose to lower the SBE-FP user fee rate to 1.75 percent for the 2022 benefit year from the 2.5 percent SBE-FP user fee rate we finalized for the 2021 benefit year. We are proposing a FFE-DE and SBE-FP-DE user fee rate of 1.5 percent for the 2023 benefit year. Subject to HHS approval, states could elect to use the FFE-DE or SBE-FP-DE options. Based on our estimated costs, enrollment (including anticipated transitions of states from the FFE and SBE-FP models to either the SBE-FP or State Exchange models), premiums for the 2021 and 2022 benefit years, and proposed user fee rates, we are estimating FFE and SBE-FP user fee transfers from issuers to the federal government would be lower by \$270 million compared to those estimated for the prior benefit year. Costs could be shifted to approve direct enrollment partners (including QHP issuers) that states elect to use, so there may not actually be any cost savings on the part of issuers in states that elect the FFE-DE or SBE-FP-DE options. As such, there might not be an incentive for issuers in states that have elected the FFE-DE or SBE-FP DE option to adopt these models solely as a result of the lower user fee rate. While there would be reduced transfers to the federal government in states that elect the FFE-DE or SBE-FP-DE options, we expect that available user fee collections from current and prior years would be sufficient to fund Exchange operations through 2023 at the proposed 2023 benefit year user fee rates. We expect that the proposed adoption of the FFE-DE and SBE-FP-DE user fee rates and the proposed decreases in

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the FFE and SBE-FP user fee rate would reduce transfers to the federal government by \$400 million in 2023.

10. Provisions Related to Cost Sharing (§ 156.130)

The PPACA provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance 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 for the 2022 benefit year. 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 2022 maximum annual limitation on cost sharing for self only coverage of \$9,100. 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.

Furthermore, we propose the premium adjustment percentage for the 2022 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 PPACA: the annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b) of the Code. We believe that the premium adjustment percentage of 1.4409174688 based on average per enrollee private health insurance premiums (excluding Medigap and property and casualty

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insurance) is well within the parameters used in the modeling of the PPACA, and we do not expect that these proposed updated values would alter CBO's May 2020 baseline projections.

We also propose that beginning with the 2023 benefit year, we would publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitations on cost sharing, and required contribution percentage in guidance in January of the calendar year preceding the benefit year to which the parameters are applicable, unless HHS is changing the methodology in which case we would do so through the applicable HHS notice of benefit and payment parameters. This proposal affects only the timing and method by which these parameters are released and would provide issuers with additional time for plan design and rate setting.

11. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

As part of the PPACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a state under section 1311 of the PPACA²⁵² to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section 1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form

²⁵² This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the PPACA. *King v. Burwell*, 576 U.S. 988 (2015).

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which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.²⁵³

On January 1, 2020²⁵⁴ and on September 11, 2020,²⁵⁵ we published notices in the **Federal Register** and solicited public comment on the burden related to the collection of information required by section 1150A of the Act. In those information collections and in this proposed rule, we fulfill this statutory requirement with the goal of imposing the least amount of burden possible while collecting data that would be usable to ensure increased transparency on prescription drug coverage in QHPs.

For example, to reduce overall burden, we seek to collect data directly from PBMs that contract with QHPs directly, rather than require QHP issuers to serve as a go-between their PBM and CMS.²⁵⁶ This approach would reduce overall burden on QHP issuers and would place the onus to report data on those entities that QHP issuers have already entrusted to oversee and manage their prescription drug line of business.

These information collections also explained how we utilize the reporting paradigm currently used by CMS' Direct and Indirect Remuneration (DIR) reporting requirement which collects, in part, the data required by section 1150A(a)(1) of the Act from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVII. We noted our intention to utilize

²⁵³ The purposes are: as the Secretary determines to be necessary to carry out section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the PPACA.

²⁵⁴ 85 FR 4993 through 4994.

²⁵⁵ 85 FR 56227 through 56229.

²⁵⁶ Under this interpretation, QHP issuers would be required to report data directly to CMS only when the QHP issuer does not contract with a PBM to administer their drug benefit. As we explained in the notices in the **Federal Register** and in this proposed rule, we are not aware of any QHP issuer which does not contract with a PBM to administer its drug benefit. Thus, we believe that there is no associated burden or regulatory impact for QHP issuers that do not contract with a PBM.

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the DIR reporting mechanisms only to the extent authorized solely by section 1150A(a)(2), explaining our understanding that DIR reporting is not authorized by section 1150A alone.²⁵⁷

Usage of these existing CMS reporting paradigms ensures minimal impact of a new data collection on QHP issuers and PBMs, given the longstanding industry use of the DIR reporting mechanism. The payer community is familiar with fulfilling the DIR reporting requirement. Therefore, we believe replicating that collection to the greatest degree would enable reporters to implement this data collection with minimal relative burden.

12. Audits of APTCs, CSRs, and User Fees (§ 156.480(c))

We are proposing to provide more clarity around the APTC, CSR, and user fee program audits and to establish authority for HHS to conduct compliance reviews to assess compliance with Federal APTC, CSR, and user fee standards through proposed amendments to § 156.480(c). Issuers being audited under the APTC, CSR, and user fee programs would be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. We are also proposing to codify our authority to recoup APTC, CSR payments, and user fee overpayments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with APTC, CSR, and user fee program audits would take 120 hours by a business operations specialist (at a rate of \$77.14 per hour), 40 hours by a computer systems analyst (at a rate of \$92.46 per hour), and 20 hours by a compliance officer (at

²⁵⁷ Except for PBM spread amount aggregated to the plan benefit package level, section 1150A imposes no additional reporting requirements for entities subject to DIR reporting. See 77 FR 22094.

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a rate of \$70.06 per hour) per issuer per benefit year. The cost per issuer would be approximately \$14,356. While the number of QHP issuers participating in the APTC, CSR, and user fee programs vary per benefit year (for example, there were 561 QHP issuers participating in the programs for the 2019 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30-60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited would be between \$430,692 and \$861,384, with an average annual cost of approximately \$646,038.

13. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

In this proposed rule, we seek comment on removing one or more levels of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We also propose to make the full QHP Enrollee Survey results publicly available in an annual PUF. We anticipate that both changes would benefit consumers and QHP issuers by increasing transparency and availability of QHP survey data through publication of a nationwide PUF, and simplifying the QRS scoring hierarchy to improve understanding of QRS quality rating information and alignment with other CMS quality reporting programs. Neither refinement would alter the data collection and reporting requirements for the QRS and QHP Enrollee Survey because QHP issuers are already required to report all data needed to support a QHP Enrollee Survey PUF and simplified QRS hierarchy. Therefore, these proposed refinements would create no additional cost or burden for QHP issuers.

14. Medical Loss Ratio (§§ 158.103, 158.130, 158.240, and 158.241)

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In this proposed rule, we propose to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i). We do not expect this proposed clarification to change the result of the regulatory impact analysis previously conducted for the HHS Notice of Benefit and Payment Parameters for 2021 with respect to the requirement that issuers deduct from MLR incurred claims not only prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer and any prescription drug rebates and other price concessions received and retained by a PBM or other entity providing pharmacy benefit management services to the issuer.

We also propose that issuers that choose to provide temporary premium credits to consumers during a declared PHE in 2021 and beyond when permitted by HHS must account for these credits as reductions to premium for the applicable months when reporting earned premium for the applicable MLR reporting year. Although we do not know how many states will permit issuers to provide temporary credits to reduce premiums or how many issuers will elect to do so, for purposes of this analysis, we previously estimated in the interim final rule on COVID-19 (85 FR 54820) that approximately 40 percent of issuers offering individual, small group or merged market health insurance coverage will provide these premium credits to reduce the premiums charged to enrollees to support continuity of coverage during the PHE for COVID-19. We do not estimate a change to the cost or burden previously estimated in that final rule, and anticipate that that regulatory impact estimate would extend to 2021 and beyond, if the provisions in this proposed rule are adopted and there are declared PHEs in the future. Although we do not know the number of issuers that would provide these temporary credits or the amount of premium credits that issuers may elect to provide, for purposes of this estimate we assume that such

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premium credits would on average constitute approximately 8 percent of total annual premium (equivalent to one month of premium), as previously estimated in the final rule. Because the MLR calculation uses three consecutive years of data, there may be additional rebate decreases in subsequent years, although the impact on rebates might be smaller as issuers would likely account for the premium relief provided to enrollees through these premium credits at the time they develop premium rates for the 2022 benefit year and other future benefit years.

We also propose to add a new § 158.240(g) to explicitly allow issuers to prepay a portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. We additionally propose to amend § 158.241(a) to allow issuers to provide rebates in form of a premium credit prior to the date that the rules currently provide. We do not expect these proposals to have a significant quantitative impact as they would not change the rebate amounts provided by issuers to enrollees. Since it is easiest and most cost-effective for issuers to conduct rebate disbursement activities all at once, the additional rebates would generally be paid during the following year's disbursement cycle – that is, if 95 percent of rebates for 2020 was prepaid during Jan-July 2021, the remainder would be paid no later than Sept. 2022 (possibly earlier in 2022 if the issuer decides to prepay again). However, we note that there may be some increased administrative burden on issuers who owe rebates remaining after prepayment associated with good faith efforts to locate enrollees, if any, with whom they no longer have a direct economic relationship.

15. State Innovation Waivers

In this proposed rule, we propose to reference and incorporate the existing 2018 Guidance in full into the section 1332 waiver implementing regulations in order to give states

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certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. This rule does not propose to alter any of the requirements related to state innovation waiver applications, compliance and monitoring, nor evaluation in a way that would create any additional cost or burden for states seeking waiver approval or those states with approved waiver plans. The Departments are of the view that the increased certainty regarding the application requirements would allow states to have greater confidence that the significant time and monetary investments necessary to plan for and submit a section 1332 waiver application would not result in wasted resources and taxpayer dollars. This could help to increase state innovation, which in turn could lead to more affordable health coverage for individuals and families in states that consider implementing a section 1332 waiver program.

16. 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.

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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 \$110.74 per hour, including overhead and fringe benefits.²⁵⁸ Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review the relevant portions of this proposed rule that causes unanticipated burden. We assume that 245 entities will review this proposed rule. For each entity that reviews the rule, the estimated cost is approximately \$110.74. Therefore, we estimate that the total cost of reviewing this regulation is approximately \$27,131 (\$110.74 x 245 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.

Under part 153 of this proposed rule, we propose to recalibrate the risk adjustment models for the 2022 benefit year using 2016, 2017, and 2018 enrollee-level EDGE data. The purpose of using these data years is to ensure that the applicable benefit year's risk adjustment

²⁵⁸ https://www.bls.gov/oes/current/oes_nat.htm.

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model coefficients can always be included in the applicable proposed and final HHS notice of benefit and payment parameters. As part of our consideration of recalibration of the risk adjustment models for the 2022 benefit year, we also considered proposing to recalibrate the risk adjustment models using the 2017, 2018, and 2019 benefit year enrollee-level EDGE data. If we had proposed that approach, we would not have been able to provide the proposed coefficients in this proposed rule and would have had to display draft coefficients only reflective of the 2017 and 2018 benefit years of enrollee-level EDGE data.

We also considered alternatives to the proposed model specification and revised enrollment duration factors to the risk adjustment models beginning with the 2022 benefit year. For example, we initially considered adding a non-linear term or HCC counts terms for all enrollees to the adult and child risk adjustment models. As described earlier in this proposed rule, we had convergence issues with the non-linear model specifications and concerns that the HCC counts terms approach posed significant gaming concerns.

In addition to the non-linear and HCC counts model specifications, we also considered alternatives to the two-stage specification and HCC interacted counts model. Specifically, we tested various alternative caps for the weights based on the distribution of costs, but found the proposed caps resulted in better prediction on average. For the prediction weights, we tested various alternative forms of weights, including reciprocals of square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of the other weights.

For the interacted HCC counts factors, we tested several HCCs and considered adding and removing certain HCCs from the proposed list in Table 3. We choose the list of HCCs in Table 3 because including these HCCs most improved prediction for enrollees with the highest

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costs, multiple HCCs, and with these specific HCCs. For the HCC interacted counts, we also considered various alternatives to structure the interacted HCC counts, such as applying individual interacted HCC counts factors (between 1-10 based on the number of HCCs an enrollee has) to each of the selected HCCs included in the models (instead of combining all of the selected HCCs into two severe and transplant indicator groups). We choose the proposed model specifications because it would add fewer additional factors to the models without sacrificing any significant predictive accuracy.

For the enrollment duration factors in the adult risk adjustment models, we propose to replace the enrollment duration factors with monthly duration factors of up to 6 months for those with HCCs. The purpose of this proposed change is to address the underprediction of plan liability for adults with HCCs. As part of this assessment, we considered whether enrollment duration factors by market type may be warranted. However, we did not find a major distinction in market-specific incremental monthly enrollment duration factor risk scores after isolating the enrollment duration factors to enrollees with HCCs.

We considered including a requirement for states to submit and be approved for a State Innovation Waiver under section 1332 of the PPACA as part of the proposed Exchange DE options. However, nothing under the plain terms of section 1311(d)(4) the PPACA governing the functions of an Exchange requires an Exchange to host a single, consumer-facing website to receive applications or support plan shopping and selection.²⁵⁹ Thus we concluded that there is no requirement in the PPACA that must be waived to allow a state to implement the DE option,

²⁵⁹ Section 1311(d)(4)(C) of the PPACA requires only that “[a]n Exchange shall, at a minimum . . . maintain an Internet website through which enrollees and prospective enrollees of qualified health plans may obtain standardized comparative information on such plans”

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and requiring states to expend taxpayer dollars to file a waiver application would be unnecessary and unduly burdensome.

We considered taking no action regarding our proposal to add a new § 155.420(a)(4)(iii)(C) in order to allow enrollees and their dependents to enroll in a new QHP of a lower metal level²⁶⁰ if they qualify for a special enrollment period due to becoming newly ineligible for APTC. However, based on questions and concerns from agents and brokers, the current policy prevents some enrollees from maintaining continuous coverage because they lose a significant amount of financial assistance that would help them purchase coverage, and cannot enroll in a new, less costly QHP of a lower metal level. HHS believes this proposal is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium.

We also considered whether to propose additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with section 155.420(d)(6)(i) or (ii) to enroll in a QHP of a higher metal level, because we recognize becoming newly eligible for APTC may increase the affordability of higher metal level plans for some individuals. However, we believe including this flexibility would largely exempt the special enrollment periods at paragraph (d)(6)(i) and (ii) from the rules at 155.420(a)(4)(iii), imposing risks of adverse selection by permitting individuals to change coverage levels in response to health status

²⁶⁰ Section 1302(d) of the PPACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the PPACA. Consumer-facing HealthCare.gov content explains that metal levels serve as an indicator of “how you and your plan split the costs of your health care,” noting that lower levels like bronze plans have lower monthly premiums but higher out of pocket costs when consumers access care, while higher levels like gold have higher monthly premiums but lower out of pocket costs to access care – see <https://www.healthcare.gov/choose-a-plan/plans-categories/>.

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changes. Furthermore, while we believe the proposed flexibilities for individuals who become newly ineligible for APTC are needed in order to promote continuous coverage for individuals who can no longer afford their original plan choice, no similar affordability and continuous coverage concerns exist for enrolled consumers who gain APTC eligibility during the coverage year. Accordingly, at this time we are not proposing additional plan flexibility for enrollees who become newly eligible for APTC.

We considered taking no action regarding our proposal to add a new § 155.420(c)(5) to allow a qualified individual, dependent or enrollee that did not receive timely notice of a triggering event or was otherwise reasonably unaware that a triggering event described in § 155.420(d) occurred to select a new plan within 60 days of the date he or she knew, or reasonably should have known, of the occurrence of the triggering event. However, in some circumstances this would result in consumers, through no fault of their own, being unable to access a special enrollment period for which they were eligible. Additionally, we considered not adding new § 155.420(b)(5) to provide a qualified individual, dependent, or enrollee described in new § 155.420(c)(5) with the option for a retroactive effective date. Failing to provide the option for a retroactive effective date would necessarily result in a gap in coverage, and therefore hinder a consumer's ability to maintain continuous coverage.

We also considered limiting the applicability of the proposal to add a new § 155.420(c)(5) to a qualified individual, enrollee, or dependent who does not receive notice or become reasonably aware of the occurrence of a triggering event until more than 15 days after the triggering event. However, failing to apply the new § 155.420(c)(5) to qualified individuals, enrollees, or dependents who receive notice or become reasonably aware of the occurrence of a triggering event 15 days or less after the triggering event and eliminating the option for a

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retroactive effective date for those individuals would result in a gap in coverage for such individuals and hinder their ability to maintain continuous coverage.

We considered taking no action regarding our proposal to add new paragraph (v) to § 155.420(d)(1) to specify that complete cessation of employer contributions to COBRA continuation coverage is a special enrollment period triggering event. However, codifying this policy in regulation provides transparency to a long-standing interpretation of the FFEs and SBE-FPs. Additionally, codifying this policy in regulation ensures alignment across all Exchanges and in the off-Exchange individual market.

We considered several alternatives to requiring that all Exchanges conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods for consumers not already enrolled in coverage through the applicable Exchange, including designating specific special enrollment period types, like Loss of Minimum Essential Coverage, that must be verified. We concluded that designating a percentage of special enrollment period enrollments that must be verified would provide Exchanges with implementation flexibility to decide the best way to conduct special enrollment period verification based on Exchange type, population characteristics, and trends. We also considered the impact of not proposing the revision requiring special enrollment period verification, but concluded that the proposed revision would have an overall positive impact on program integrity by reducing the risk of ineligible consumers enrolling in Exchange coverage through a special enrollment period.

For our proposals to revise § 156.295 and add § 184.50 to require certain prescription drug reporting, we considered, but did not yet require, the reporting of data described in section 1150A(b)(1) broken down by pharmacy type (which includes an independent pharmacy, chain

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pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). As mentioned above, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files. While we believe the imposition of this level of reporting would impose unreasonable burden at this time, we intend to begin collecting this information in the future.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, et seq.), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the 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 program, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical

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Centers) and, if this is the case, the SBA size standard would be \$35 million or less.²⁶¹ 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 report²⁶² submissions for the 2019 MLR reporting year, approximately 77 out of 479 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 67 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$41.5 million. Therefore, we do not expect the proposed provisions of this rule to affect a substantial number of small entities.

In this proposed rule, we propose requiring certain QHP issuers or their PBMs to report certain prescription drug information to CMS. We are not aware of any QHP issuer or PBM that contracts with a QHP issuer to administer their prescription drug benefit which would be considered a “small entity” under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under title XVIII, title XIX, or part B of title 42 of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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. While this rule is not subject to section 1102 of the Act, we have

²⁶¹ <https://www.sba.gov/document/support--table-size-standards>.

²⁶² Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

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determined that this proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this rule 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 actions before issuing a proposed rule that includes any federal mandate that may result in expenditures in any one year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$156 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. 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.

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

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states, including participating in conference calls with and attending conferences of the NAIC, and consulting with state insurance officials on an individual basis.

While developing this rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. A user fee is assessed on issuers under all existing Exchange models, including State Exchanges where the user fee is assessed by the state, SBE-FPs, and the FFEs. We have solicited comment on the proposed user fee rate of 1.5 percent of monthly premiums or issuers in Exchanges that adopt the newly proposed FFE-DE and SBE-FP-DE options.

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

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Comptroller for review. This proposed rule, if finalized as proposed, is expected to be 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 regulatory action. We estimate costs of approximately \$52.45 million in 2021, cost savings of approximately \$72.08 million in 2022, costs of approximately \$40.92 in 2023 and annual costs of approximately \$6.32 million thereafter. Thus the annualized value of costs, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, would be \$4.65 million.

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List of Subjects31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements, Waivers for State Innovation.

45 CFR Part 147

Age discrimination, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 150

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Age discrimination, Brokers, Civil rights, Citizenship and naturalization, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Technical assistance, Taxes, Women, Youth.

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45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 184

Administrative practice and procedure, Consumer protection, Health care, Health insurance, Health maintenance organization (HMO), Organization and functions (Government agencies), Prescription Drugs, Reporting and recordkeeping requirements.

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For the reasons set forth in the preamble, the Department of the Treasury amends 31 CFR subtitle A as set forth below:

PART 33 – WAIVERS FOR STATE INNOVATION

1. The authority citation for part 33 continues to read as follows:

Authority: Sec. 1332, Pub. L. 111-148, 124 Stat. 119.

2. Section 33.108 is amended by revising paragraph (f)(3)(iv) introductory text to read as follows:

§ 33.108 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of Health and Human Services, as applicable, with the necessary data to determine that the State’s proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with guidance published by the Secretary and the Secretary of Health and Human Services at 83 FR 53575 (Oct. 24, 2018):

* * * * *

3. Section 33.120 is amended by revising paragraph (a)(1) to read as follows:

§ 33.120 Monitoring and compliance

(a) * * *

(1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, as applicable, a State must comply

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with all applicable Federal laws, regulations, and interpretive policy statements, as well as guidance published by the Secretary and the Secretary of Health and Human Services at 83 FR 53575 (Oct. 24, 2018), unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

* * * * *

4. Section 33.128 is amended by revising paragraph (a) to read as follows:

§ 33.128 Periodic evaluation requirements.

(a) The Secretary and the Secretary of Health and Human Services, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of Health and Human Services, including the guidance published at 83 FR 53575 (Oct. 24, 2018), as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

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For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 147 – HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL INSURANCE MARKETS

5. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

6. Section 147.104 is amended by revising paragraphs (b)(2)(ii) and (4)(ii) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(2) * * *

(ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in §§ 155.420(a)(5) and 155.420(d)(4)) of this subchapter to a “QHP” is deemed to refer to a plan, a reference to “the Exchange” is deemed to refer to the applicable State authority, and a reference to a “qualified individual” is deemed to refer to an individual in the individual market. For purposes of § 155.420(d)(4) of this subchapter “the Exchange” is deemed to refer to the Exchange or the health plan, as applicable.

* * * * *

(4) * * *

(ii) In the individual market, subject to § 155.420(c)(5) of this subchapter, individuals must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and

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(3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in § 155.420(c)(2) of this subchapter.

* * * * *

PART 150 – CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE

MARKETS

7. The authority citation for part 150 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

§ 150.103 [Amended]

8. Section 150.103 is amended in the definition of “Complaint” by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.205 [Amended]

9. Section 150.205 is amended in paragraph (e)(2) by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.213 [Amended]

10. Section 150.213 is amended in paragraph (b) by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.303 [Amended]

11. Section 150.303 is amended in paragraph (a) introductory text by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.305 [Amended]

12. Section 150.305 is amended in paragraphs (a)(1), (a)(2), (b)(1), and (c)(1) by removing the word “HIPAA” each time it appears and adding in its place “PHS Act”.

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§ 150.311 [Amended]

13. Section 150.311 is amended in paragraph (g) by removing the word “HIPAA” and adding in its place “PHS Act”.

§ 150.313 [Amended]

14. Section 150.313 is amended in paragraph (b) by removing the word “HIPAA” and adding in its place “PHS Act”.

15. Section 150.401 is amended by revising the definitions of “Filing date” and “Hearing” to read as follows:

§ 150.401 Definitions.

* * * * *

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

* * * * *

16. Section 150.419 is amended by revising paragraph (a) to read as follows:

§ 150.419 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness’ direct testimony in writing only if the witness is available for cross-examination.

* * * * *

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17. Section 150.427 is amended by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 150.427 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

18. Section 150.431 is revised to read as follows:

§ 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

19. Section 150.441 is amended by revising paragraph (e) to read as follows:

§ 150.441 Prehearing conferences.

* * * * *

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

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* * * * *

20. Section 150.447 is amended by revising paragraph (a) to read as follows:

§ 150.447 The record.

(a) Any testimony that is taken in-person, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

* * * * *

PART 153 – STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

21. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

22. Section 153.320 is amended by—

- a. Revising paragraph (c);
- b. Redesignating paragraphs (d)(2) through (d)(4) as paragraphs (d)(3) through (d)(5), respectively;
- c. Adding new paragraph (d)(2);
- d. Revising newly designated paragraphs (d)(4) and (d)(5)(i); and
- e. Adding paragraphs (d)(5)(iii) through (v).

The revisions and additions read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in notice and comment rulemaking by HHS in advance of the applicable benefit

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year, the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

(d) * * *
* * * *

(2) Beginning with the 2023 benefit year, States may request a reduction to otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology for up to 3 years.

(i) A State making a multi-year request must:

(A) Submit evidence and analysis as set forth in paragraphs (d)(1)(i) through (iii) of this section, as applicable, for all years to which the request would apply.

(B) Include with its request a confirmation that it does not anticipate any significant changes to the State market risk pool(s) impacted by its request for the duration for which it is requesting a reduction in risk adjustment transfers.

(C) Respond to HHS requests for supplemental evidence under paragraph (d)(5)(iv) of this section, in the form, manner, and timeframe specified by HHS.

(ii) A State may withdraw its multi-year state reduction request prior to the natural expiration of the request by notifying HHS of its intent to withdraw the request, in the form and manner specified by HHS, 60 calendar days prior to the applicable benefit year’s rate setting deadline. The State must also notify its impacted issuers of the withdrawal of its multi-year reduction request at least 45 calendar days prior to the applicable benefit year’s rate setting deadline.

* * * *

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(4) *Publication of reduction requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters and make the supporting evidence available to the public for comment, except to the extent the State requests HHS not publish certain supporting evidence because it contains trade secrets or confidential commercial or financial information as defined in HHS' Freedom of Information regulations under 45 CFR 5.31(d). HHS will publish any approved or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule. Beginning with the 2023 benefit year, all multi-year State reduction requests will be published in the annual HHS notice of benefit and payment parameters that correspond with the first year in which the multi-year flexibility was requested.

(5) * * *

(i) Subject to paragraphs (d)(5)(ii) and (iii) of this section, HHS will approve State reduction requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market risk pool, and other relevant public comments:

* * * * *

(iii) For multi-year requests, HHS may approve a duration that is shorter than what was requested by the State for a multi-year reduction request if HHS determines that the supporting evidence and analysis do not fully support the requested duration.

(iv) HHS may request supplemental evidence from a State with an approved multi-year reduction request at any time after its initial approval, in the form and manner specified by HHS.

(v) HHS retains the ability to terminate or modify a previously approved multi-year reduction request at any time after its initial approval if new additional data or information does

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not support the continuation of the State's reduction request and the State has not provided sufficient supplemental evidence to rebut such data or information. If the request is terminated or modified by HHS, the State must notify its impacted issuers of the termination or modification of its multi-year reduction request within 15 calendar days of the state's receipt of HHS's notice of termination or modification of its previously approved reduction request.

23. Section 153.410 is amended by revising paragraph (d) to read as follows:

§ 153.410 Requests for reinsurance payment.

* * * * *

(d) *Audits and Compliance Reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.

(1) *Notice of Audit.* HHS will provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with Audit Activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

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(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described in paragraph (d)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (d)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (d)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

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(4) *Final Audit Findings*. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to Comply with Audit Activities*. If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of reinsurance payments received that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (5)(i) of this section if the reinsurance debt is not paid.

24. Section 153.620 is amended by revising paragraph (c) to read as follows:

§ 153.620 Compliance with risk adjustment standards.

* * * * *

(c) *Audits and Compliance Reviews*. HHS or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with respect to the applicable requirements in this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.

(1) *Notice of Audit*. HHS will provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan.

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(i) *Conferences*. All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with Audit Activities*. To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the audit entrance conference described in paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

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(3) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final Audit Findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to Comply with Audit Activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of the risk adjustment (including high-cost risk pool) payments that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any risk adjustment (including high-cost risk pool) payments identified in paragraph (c)(5)(i) of this section.

25. Section 153.630 is amended by—

- a. Revising paragraphs (d)(2) and (3); and
- b. Adding paragraphs (g)(4) and (5).

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The revisions read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(d) * * *

(2) Within 15 calendar days of the notification by HHS of the findings of a second validation audit (if applicable) or the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.

(3) An issuer may appeal the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as result of risk adjustment data validation, under the process set forth in § 156.1220 of this subchapter.

* * * * *

(g) * * *

(4) The issuer only offered small group market carryover coverage during the benefit year that is being audited.

(5) The issuer was the sole issuer in the state market risk pool during the benefit year that is being audited and did not participate in any other market risk pools in the State during the benefit year that is being audited.

26. Section 153.710 is amended—

a. By redesignating paragraphs (e) through (g), as paragraphs (f) through (h), respectively; and

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- b. By adding a new paragraph (e); and
- c. In newly redesignated paragraph (h) introductory text by removing the reference “paragraph (g)(3)” and adding in its place the reference “paragraph (h)(3)”.

The addition reads as follows:

§ 153.710 Data requirements.

* * * * *

(e) *Materiality Threshold.* HHS will consider a discrepancy reported under paragraph (d)(2) of this section to be material if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or \$100,000, whichever is less.

* * * * *

PART 155 – EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

27. 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.

28. Section 155.20 is amended by--

- a. Adding the definitions of “Agent or broker direct enrollment technology provider” and “Qualified health plan issuer direct enrollment technology provider”;
- b. Revising the definitions of “Web-broker”.

The additions and revision read as follows:

§ 155.20 Definitions.

* * * * *

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Agent or broker direct enrollment technology provider means a type of web-broker business entity that is not a licensed agent or broker under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221.

* * * * *

Qualified health plan issuer direct enrollment technology provider means a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 or 156.1230, including a web-broker that provides services as a direct enrollment technology provider to QHP issuers. A QHP issuer direct enrollment technology provider that provides technology services or provides access to an information technology platform to a QHP issuer will be a downstream or delegated entity of the QHP issuer that participates or applies to participate as a direct enrollment entity.

* * * * *

Web-broker means an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221. The term also includes an agent or broker direct enrollment technology provider.

29. Section 155.205 is amended by revising paragraphs (c)(2)(i)(B), (c)(2)(iii)(B), (c)(2)(iv) introductory text, (c)(2)(iv)(B) and (C) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

* * * * *

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(c) * * *

(2) * * *

(i) * * *

(B) For a web-broker, beginning November 1, 2015, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, this standard also includes telephonic interpreter services in at least 150 languages.

* * * * *

(iii) * * *

(B) For a web-broker, beginning when such entity has been registered with the Exchange for at least 1 year, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Web site content or documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if they are required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. A web-broker that is licensed in and serving multiple States may aggregate the limited English populations in the States it serves to determine the top 15 languages required for taglines. A web-broker may satisfy tagline requirements with respect to Web site content if it posts a Web link prominently on its home page that directs individuals to the full text of the taglines indicating how individuals may obtain language

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assistance services, and if it also includes taglines on any critical stand-alone document linked to or embedded in the Web site.

(iv) For Exchanges, QHP issuers, and web-brokers, Web site translations.

* * * * *

(B) For a QHP issuer, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, or, in cases where a QHP issuer is participating in the enhanced direct enrollment program, twelve (12) months from the date the QHP issuer begins operating its enhanced direct enrollment website in the relevant state for the Web site content that must be added to its Web site as a condition of participation in the FFE enhanced direct enrollment program. If the content of a Web site maintained by the QHP issuer is critical for obtaining health insurance coverage or access to health care services through a QHP within the meaning of § 156.250 of this subchapter, it must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

(C) For a web-broker, beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least one year, whichever is later, or, in cases where a web-broker is participating in the enhanced direct enrollment program, twelve (12) months from the date the web-broker begins operating its enhanced direct enrollment Web site in the relevant state for the Web site content added to its Web site to participate in the FFE enhanced direct enrollment program, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a Web site that is maintained by the web-broker must be translated into any non-English language that is spoken by a limited English proficient population that comprises 10

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percent or more of the population of the relevant State, as determined in guidance published by the Secretary, except that when a web-broker operates in a State using a direct enrollment model under § 155.221(j) of this subpart, the web-broker must translate website content consistent with this paragraph as soon as it begins operations in the State.

* * * * *

30. Section 155.220 is amended by—

- a. Revising paragraphs (c)(3)(i)(A) and (D);
- b. Adding paragraph (c)(3)(iii); and
- c. Adding paragraphs (c)(6) and (n).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), except as permitted under paragraph (n) of this section;

* * *

(D) Display all QHP data provided by the Exchange, except as permitted under paragraph (n) of this section;

* * * * *

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(iii)(A) Notwithstanding paragraph (n)(1) of this section, when permitted under State law, Navigators and certified application counselors may use the Web site of a web-broker to assist an applicant to enroll in a QHP offered through the Exchange, including to assist an applicant to complete the Exchange eligibility application, if the Web site displays all QHP data provided by the Exchange related to all QHPs offered through the Exchange consistent with the requirements of § 155.205(b)(1) and (c). Navigators and certified application counselors may use a web-broker Web site that does not facilitate enrollment in all QHPs offered through the Exchange, so long as the Web site identifies such QHPs to consumers by prominently displaying a standardized disclaimer provided by the Exchange, and in the manner and form specified by the Exchange, stating that enrollment in such QHPs can be completed through the Exchange Web site and providing a link to the Exchange Web site.

(B) A web-broker that makes its Web site available for use by Navigators and certified application counselors, consistent with the requirements in paragraph (c)(3)(iii)(A) of this section may complete an annual certification process with the Exchange, in the manner and form specified by the Exchange, by attesting to its compliance with the requirements in paragraph (c)(3)(iii)(A) of this section.

* * * * *

(6) In addition to applicable requirements under § 155.221(b)(4), a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's internet Web site being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

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(i) Operational data including licensure information, points of contact, and third-party relationships;

(ii) Enrollment testing, prior to approval or renewal;

(iii) Website reviews performed by HHS;

(iv) Security and privacy assessment documentation, including:

(A) Penetration testing results;

(B) Security and privacy assessment reports;

(C) Vulnerability scan results;

(D) Plans of action and milestones; and

(E) System security and privacy plans.

(v) Agreements between the web-broker and HHS.

* * * * *

(n) *Exception.* (1) Except in cases where the Web site of a web-broker is intended to be available for use by Navigators and certified application counselors consistent with paragraph (c)(3)(iii)(A) of this section, if the Web site of a web-broker does not support enrollment in a QHP offered through an Exchange, the web-broker is not required to provide all of the standardized comparative information required under § 155.205(b)(1) for that QHP, but the web-broker's Web site must instead:

(i) Prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange Web site;

(ii) Provide a Web link to the Exchange Web site; and

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(iii) Display the following minimum QHP information consistent with the requirements of § 155.205(c): issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information.

(2) [Reserved]

31. Section 155.221 is amended—

- a. By revising paragraphs (b)(1), (3), and (4);
- b. By redesignating paragraphs (c) through (h) as paragraphs (d) through (i), respectively.
- c. By adding paragraphs (c) and (j);
- d. By revising newly redesignated paragraphs (g) introductory text, (g)(6), (g)(7), and (h) by removing the reference to “paragraph (e)” and adding in its place a reference to “paragraph (f)”; and
- e. By adding paragraph (j).

The additions and revisions read as follows:

§ 155.221 Standards for direct enrollment entities and for third parties to perform audits of direct enrollment entities.

* * * * *

(b) * * *

(1) Display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products, such as excepted benefits, on at least three separate website pages on its non-Exchange Web site, except as permitted under paragraph (c) of this section;

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* * * * *

(3) Limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under paragraph (c)(1) of this section;

(4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet Web site being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

(i) Business audit documentation including:

(A) Notices of intent to participate including auditor information;

(B) Documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and

(C) Business audit reports including testing results.

(ii) Security and privacy audit documentation including:

(A) Interconnection security agreements;

(B) Security and privacy controls assessment test plans;

(C) Security and privacy assessment reports;

(D) Plans of action and milestones;

(E) Privacy impact assessments;

(F) System security and privacy plans;

(G) Incident response plans; and

(H) Vulnerability scan results.

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- (iii) Eligibility application audits performed by HHS;
- (iv) Online training modules offered by HHS; and
- (v) Agreements between the direct enrollment entity and HHS.

* * * * *

(c) Exceptions to direct enrollment entity display and marketing requirement. For the Federally-facilitated Exchanges, a direct enrollment entity may:

(1) Display and market QHPs offered through the Exchange and individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement as described in § 146.123(c) of this subchapter, as a standalone benefit, or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage health reimbursement arrangement using a salary reduction arrangement pursuant to a cafeteria plan under section 125 of the Internal Revenue Code, but must clearly distinguish between the QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicate that advance payments of the premium tax credit and cost-sharing reductions are available only for QHPs purchased through the Exchange, that advance payments of the premium tax credit are not available to individuals who accept an offer of an individual coverage health reimbursement arrangement or who opt out of an individual coverage health reimbursement arrangement that is considered affordable, and that a salary

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reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange; and

(2) Display and market Exchange-certified stand-alone dental plans offered outside the Exchange and non-certified stand-alone dental plans on the same website pages.

* * * * *

(j) *Process for States to elect the Exchange Direct Enrollment Option.* Subject to HHS approval, and in addition to or in lieu of the Exchange in the State operating its own consumer-facing eligibility application and enrollment website, a State may elect for the State Exchange, State Exchange on the Federal platform, or Federally-facilitated Exchange in the State to approve one or more enrollment entities described in paragraph (a) of this section to make available a non-Exchange online website to enroll qualified individuals in a QHP offered through the Exchange in the State in a manner that constitutes enrollment through the Exchange, as specified in paragraphs (j)(1) or (2) of this section. Through these approved entities consumers in the State apply for coverage using an eligibility verification and enrollment application as described in § 155.405, and receive eligibility determinations from the Exchange for QHP enrollment, advance payments of the premium tax credit and cost-sharing reductions, as well as receive assessments or determinations from the Exchange for Medicaid and CHIP eligibility in accordance with §§ 155.302 and 155.405.

(1) *Direct Enrollment Option for a State Exchange.* A State may receive approval, under §§ 155.105(b) and 155.106(a), to operate a State Exchange using the direct enrollment option described in paragraph (j) of this section. The State Exchange must meet all federal statutory and regulatory requirements for the operation of an Exchange. An approved State Exchange that wishes to implement this option must submit a revised Exchange Blueprint in accordance with §

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155.105(e). In order to obtain approval for the State Exchange to implement this option, the State must:

(i) Demonstrate to HHS operational readiness for the State Exchange and its proposed direct enrollment entities to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and to enable individuals to apply for, and receive eligibility determinations for QHP enrollment, advance payments of the premium tax credit and cost-sharing reductions for QHPs from the Exchange, as well as receive assessments or determinations of Medicaid and CHIP eligibility from the Exchange as described in § 155.302, using the eligibility verification and enrollment application described in § 155.405;

(ii) Provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities; and

(iii) Ensure that a minimum of one direct enrollment entity approved by the State meets minimum federal requirements for HHS approval to participate in the Federally-facilitated Exchange direct enrollment program, including requirements at 45 CFR 155.220 and 155.221, and is capable of enrolling all consumers in the State, including those who present complex eligibility scenarios. Where no direct enrollment entity approved by the State meets such minimum federal requirements or possesses the capability to enroll all consumers in the State, the State must offer a consumer-facing website that meets such requirements and possess such capability.

(2) *Direct enrollment option for a State with a Federally-facilitated Exchange or State Exchange on the Federal platform.* Pursuant to a request from a State, the Federally-facilitated Exchange or a State Exchange on the Federal platform may partner with the requesting State to

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implement the direct enrollment option described in this paragraph (j). The Federally-facilitated Exchange or State-based Exchange on the Federal platform must meet all federal statutory and regulatory requirements for the operation of an Exchange. In order to obtain approval for the Federally-facilitated Exchange or State Exchange on the Federal platform in a State to implement this option, a State must:

(i) Coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the State, necessary for the Federally-facilitated Exchange to operationalize the necessary changes to implement this option;

(ii) Execute a Federal agreement with HHS that includes the terms and conditions for the arrangement and which defines the division of responsibilities between HHS and the State;

(iii) Agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) of this subchapter; and

(iv) Perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act, including complying with reporting and compliance activities required by HHS and described in the Federal agreement.

32. Section 155.420 is amended by—

- a. Revising paragraph (a)(4)(ii)(B);
- b. Adding paragraph (a)(4)(ii)(C);
- c. Revising paragraph (a)(4)(iii) introductory text;
- b. Adding paragraphs (b)(5) and (c)(5);
- c. Revising paragraphs (d)(1)(iii) and (iv);

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- d. Adding paragraph (d)(1)(v);
- e. Adding paragraphs (f) and (g).

The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

- (a) * * *
- (4) * * *
- (ii) * * *

(B) Beginning January 2022, if an enrollee and his or her dependents become newly ineligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a QHP one metal level higher or lower, if they elect to change their QHP enrollment; or

(C) If an enrollee and his or her dependents become newly ineligible for advance payments of the premium tax credit in accordance with paragraph (d)(6)(i) or (ii) of this section, the Exchange must allow the enrollee and his or her dependents to change to a QHP of a lower metal level, if they elect to change their QHP enrollment;

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), (d)(6)(i) and (ii) of this section for becoming newly eligible or ineligible for CSRs or newly ineligible for APTC, (d)(8), (9), (10) and (12) of this section:

- * * * * *
- (b) * * *

(5) *Option for earlier effective dates due to untimely notice of triggering event.* At the option of a qualified individual, enrollee or dependent who is eligible to select a plan during a

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period provided for under paragraph (c)(5) of this section, the Exchange must provide the earliest effective date that would have been available under paragraph (b) of this section, based on the applicable triggering event under paragraph (d) of this section.

(c) * * *

(5) *Availability for individuals who did not receive timely notice of triggering events.* If a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event described in paragraph (d) of this section occurred, the Exchange must allow the qualified individual, enrollee, or when applicable, his or her dependent to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event.

* * * * *

(d) * * *

(1) * * *

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)) or loses access to health care services through coverage provided to a pregnant woman's unborn child, based on the definition of a child in 42 CFR 457.10. The date of the loss of coverage is the last day the qualified individual would have pregnancy-related coverage or access to health care services through the unborn child coverage;

(iv) Loses medically needy coverage as described under section 1902(a)(10)(C) of the Act only once per calendar year. The date of the loss of coverage is the last day the consumer would have medically needy coverage; or

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(v) Is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums and the employer completely ceases its contributions to the qualified individual's or dependent's COBRA continuation coverage. The triggering event is the last day of the period for which COBRA continuation coverage is paid for, in whole or in part, by an employer. (See 26 CFR 54.9801-6(a)(3)(ii) for rules regarding termination of employer contributions toward coverage other than COBRA continuation coverage, including coverage under a similar State program.)

* * * * *

(f) *Special enrollment period verification.* Unless a request for modification is granted in accordance with § 155.315(h), an Exchange must conduct verification of applicants' eligibility for special enrollment periods under this section. An Exchange meets this requirement if it verifies eligibility for a number of individuals newly enrolling in Exchange coverage through special enrollment periods that equals at least 75 percent of all special enrollment periods for individuals newly enrolling in Exchange coverage. If the Exchange is unable to verify eligibility for individuals newly enrolling in Exchange coverage through a special enrollment period for which the Exchange requires verification, then the individuals are not eligible for enrollment through the Exchange. In accordance with § 155.505b(iii), individuals have the right to appeal the eligibility determination.

33. Section 155.726 is amended by revising paragraph (c)(2)(i) to read as follows:

§ 155.726 Enrollment periods under SHOP for plan years beginning on or after January 1, 2018.

* * * * *

(c) * * *

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(2) * * *

(i) Experiences an event described in § 155.420(d)(1) (other than paragraphs (d)(1)(ii) and (v)), or experiences an event described in § 155.420(d)(2), (4), (5), (7), (8), (9), (10), (11), or (12);

* * * * *

34. Section 155.1308 is amended by revising paragraph (f)(3)(iv) introductory text to read as follows:

§ 155.1308 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with guidance published by the Secretary and the Secretary of the Treasury at 83 FR 53575 (Oct. 24, 2018):

* * * * *

35. Section 155.1320 is amended by revising paragraph (a)(1) to read as follows:

§ 155.1320 Monitoring and compliance

(a) * * *

(1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all

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applicable Federal laws, regulations, and interpretive policy statements, as well as guidance published by the Secretary and the Secretary of the Treasury at 83 FR 53575 (Oct. 24, 2018), unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

* * * * *

36. Section 155.1328 is amended by revising paragraph (a) to read as follows:

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of the Treasury, including the guidance published at 83 FR 53575 (Oct. 24, 2018), as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

PART 156 – HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

37. 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.

38. Section 156.50 is amended by—

- a. Revising the heading for paragraph (c);
- b. Revising paragraph (c)(2);
- c. Adding paragraph (c)(3);

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- d. Revising the heading for paragraph (d); and
- e. Revising paragraphs (d)(1) introductory text, (d)(2) introductory text , (d)(2)(i)(A), (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3) introductory text, (d)(4) through (6), and (d)(7) introductory text;

The revisions and addition read as follows:

§ 156.50 Financial support.

* * * * *

(c) *Requirement for Exchange user fees.* * * *

(2) To support the functions of State-based Exchanges on the Federal platform, unless the State-based Exchange and HHS agree on an alternative mechanism to collect the funds, a participating issuer offering a plan through a State-based Exchange on the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State-Based Exchanges on the Federal platform for the applicable benefit year, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

(3) A participating issuer offering a plan through an State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option as described in § 155.221(j) of this subchapter, as specified in a Federal agreement with HHS, must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate for the

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applicable benefit year specified in an annual HHS notice of benefit and payment parameters published in advance of the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option.

(d) *Adjustment of Exchange user fees.*

(1) A participating issuer offering a plan through a Federally-facilitated Exchange or State-based Exchange on the Federal platform may qualify for an adjustment of the Federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section, the State-based Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, or the user fee specified in paragraph (c)(3) of this section, applicable to issuers participating in a State-based Exchange on the Federal platform or a Federally-facilitated Exchange that has adopted the direct enrollment option under § 155.221(j) of this subchapter, the extent that the participating issuer –

* * * * *

(2) For a participating issuer described in paragraph (d)(1) of this section to receive an adjustment of a user fee under this section –

(i) * * *

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

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(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable; and

* * * * *

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federally-facilitated Exchange user fee, the State-based Exchange on the Federal platform user fee, or the user fee applicable to issuers participating in a State-based Exchange on the Federal platform or a Federally-facilitated Exchange that has adopted the direct enrollment option § 155.221(j) of this subchapter based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4).

(iii) * * *

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable;

* * * * *

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(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, equal in value to the sum of the following:

* * * * *

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment of a user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1), (2), or (3) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it

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timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

* * * * *

39. Section 156.130 is amended by revising paragraph (e) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(e) *Premium adjustment percentage.* The premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. HHS will publish the annual premium adjustment percentage in guidance in January of the calendar year preceding the benefit year for which the premium adjustment percentage is applicable, unless HHS proposes changes to the methodology, in which case, HHS will publish the annual premium adjustment percentage in an annual HHS notice of benefit and payment parameters or another appropriate rulemaking.

* * * * *

40. Section 156.230 is amended by adding paragraph (f) to read as follows:

§156.230 Network adequacy standards.

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* * * * *

(f) Paragraphs (a) through (e) of this section do not apply to a plan for which an issuer seeks QHP certification or to any certified QHP that does not use a provider network, meaning that the plan or QHP does not condition or differentiate benefits based on whether the issuer has a network participation agreement with the provider that furnishes the covered services.

41. Section 156.295 is amended by—

- a. Revising the section heading and paragraphs (a) introductory text, (a)(1) and (a)(2) introductory text,
- b. Removing paragraph (a)(3); and
- c. Revising paragraph (b) introductory text.

The revisions read as follows:

§ 156.295 Prescription drug distribution and cost reporting by QHP issuers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a QHP issuer that administers a prescription drug benefit without the use of a pharmacy benefit manager must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:

This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

* * * * *

(b) *Limitation on disclosure.* Information disclosed by a QHP issuer under this section shall not be disclosed by HHS, except that HHS may disclose the information in a form which does not disclose the identity of a specific QHP or prices charged for specific drugs, for the following purposes:

* * * * *

42. Section 156.420 is amended by revising paragraphs (a)(1)(i), (a)(2)(i) and (a)(3)(i) to read as follows:

§ 156.420 Plan variations.

(a) * * *

(1) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * *

(2) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * *

(3) * * *

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(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * *

43. Section 156.480 is amended by revising the section heading and paragraph (c) to read as follows:

§ 156.480 Oversight of the administration of the advance payments of the premium tax credit, cost-sharing reductions, and user fee programs.

* * * * *

(c) *Audits and Compliance Reviews.* HHS or its designee may audit or conduct a compliance review of an issuer offering a QHP through an Exchange to assess its compliance with the applicable requirements of this subpart and 45 CFR 156.50. Compliance reviews conducted under this section will follow the standards set forth in § 156.715.

(1) *Notice of Audit.* HHS will provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer under this section.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with Audit Activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

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(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described under paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (c)(2)(ii) or (iii), as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (c)(2)(ii) or (iii), as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

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(4) *Final Audit Findings*. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 30 calendar days of the issuance of the final audit or compliance review report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to Comply with Audit Activities*. If an issuer fails to comply with the audit activities set forth in this section in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of payments received under this subpart that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (c)(5)(i) of this section if a premium tax credit, cost-sharing reductions, and user fee program debt is not paid.

(6) *Circumstances Requiring HHS Enforcement*. If HHS determines that the State Exchange or State-based Exchange on the Federal platform is not enforcing or fails to substantially enforce the requirements of this subpart or 45 CFR 156.50, then HHS may do so and may pursue the imposition of civil money penalties as specified in § 156.805 for non-compliance by QHP issuers participating in the State Exchange or State Exchange on the Federal platform.

44. Part 156, Subpart I is amended by revising the title of this subpart as follows:

Subpart I – Enforcement Remedies in the Exchanges

* * * * *

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45. Section 156.800 is amended by revising paragraphs (a) introductory text, and (b) as follows:

§ 156.800 Available remedies; Scope.

(a) *Kinds of sanctions.* HHS may impose the following types of sanctions on QHP issuers in an Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in an Exchange:

* * * * *

(b) *Scope.* Sanctions under subpart I are applicable for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange. Sanctions under paragraph (a)(1) of this section are also applicable for non-compliance by QHP issuers participating in State Exchanges and State-based Exchanges on the Federal platform when HHS is responsible for enforcement of the requirements in subpart E of this part and 45 CFR 156.50.

* * * * *

46. Section 156.805 is amended by—

- a. Revising paragraphs (a) introductory text and (a)(5)(i); and
- b. Adding new paragraph (f) to read as follows:

The revisions and addition read as follows:

§ 156.805 Bases and process for imposing civil money penalties in Exchanges.

(a) *Grounds for imposing civil money penalties.* Civil money penalties may be imposed on an issuer in an Exchange if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

* * * * *

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(5) * * *

(i) To HHS or an Exchange; or

* * * * *

(f) *Circumstances requiring HHS enforcement in State Exchanges and State-based Exchanges on the Federal platform.*

(1) HHS will enforce the requirements of subpart E of this part and 45 CFR 156.50 if a State Exchange or State-based Exchange on the Federal platform notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201 *et seq.* that a State Exchange or State-based Exchange on the Federal platform is failing to substantially enforce these requirements.

(2) If HHS is responsible under paragraph (f)(1) of this section for enforcement of the requirements set forth in subpart E of this part or 45 CFR 156.50, HHS may impose civil money penalties on an issuer in a State Exchange or State-based Exchange on the Federal platform, in accordance with the bases and process for imposing civil money penalties set forth in this section.

47. Part 156, Subpart J is amended by revising the subpart heading to read as follows

Subpart J - Administrative Review of QHP Issuer Sanctions

* * * * *

48. Section 156.901 is amended by revising the definitions of “Filing date” and “Hearing” to read as follows.

§ 156.901 Definitions.

* * * * *

Filing date means the date filed electronically.

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Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

* * * * *

49. Section 156.903 is amended by revising paragraph (a) as follows:

§ 156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty of a QHP offered in a Federally-facilitated Exchange, State Exchange, and State-based Exchange on the Federal platform, or the decertification of a QHP offered in a Federally-facilitated Exchange.

* * * * *

50. Section 156.919 is amended by revising paragraph (a) to read as follows:

§ 156.919 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

* * * * *

51. Section 156.927 is amended by revising paragraphs (a) introductory text and (b) to read as follows:

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§ 156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

52. Section 156.931 is revised to read as follows:

§ 156.931 Acknowledgement of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

53. Section 156.941 is amended by revising paragraph (e) to read as follows:

§ 156.941 Prehearing conferences.

* * * * *

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

* * * * *

54. Section 156.947 is amended by revising paragraph (a) to read as follows:

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§ 156.947 The record.

(a) Any testimony that is taken in-person, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

* * * * *

55. Section 156.1210 is amended by--

- a. Redesignating paragraph (b) as paragraph (d); and
- b. Adding new paragraphs (b) and (c).

The additions read as follows:

§ 156.1210 Dispute submission.

* * * * *

(b) *Inaccuracies identified after 90-day period.* With respect to an inaccuracy described under paragraph (a) of this section that is identified and submitted to HHS by the issuer after the end of the 90-day period described in such paragraph, HHS will consider and work with the issuer to resolve the inaccuracy so long as—

(1) The issuer promptly notifies HHS upon identifying the inaccuracy, but in no case later than 15 calendar days after identifying the inaccuracy; and

(2) The failure to identify the inaccuracy and submit it to HHS in a timely manner was not unreasonable or due to the issuer's misconduct or negligence.

(c) *Deadline for describing inaccuracies.* To be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before the later of —

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(1) The end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates; or

(2) The date by which HHS notifies issuers that the HHS audit process with respect to the plan year to which such inaccuracy relates has been completed.

(3) If a payment error is discovered after the timeframes set forth in paragraph (c)(1) and (2) of this section, the issuer must notify HHS and repay any overpayments.

* * * * *

56. Section 156.1215 is amended by revising paragraph (b) to read as follows:

§ 156.1215 Payment and collections processes.

* * * * *

(b) Netting of payments and charges for later years. As part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federally-facilitated Exchange user fees, payment of State-based Exchanges utilizing the Federal platform user fees, and risk adjustment, reinsurance, and risk corridors payments and charges.

* * * * *

57. Section 156.1220 is amended by—

- a. Revising paragraphs (a)(1)(vii) and (a)(3)(ii);
- b. Redesignating paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively; and

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c. Adding new paragraph (a)(3)(iii).

The revision and addition reads as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(1) * * *

(vii) The findings of a second validation audit as a result of risk adjustment data validation (if applicable) with respect to risk adjustment data for the 2016 benefit year and beyond; or

* * * * *

(3) * * *

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

(iii) For the findings of a second validation audit (if applicable), or the calculation of a risk score error rate as a result of risk adjustment data validation, within 30 calendar days of publication of the applicable benefit year’s Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers;

* * * * *

58. Section 156.1240 is amended by adding paragraph (a)(3) to read as follows:

§ 156.1240 Enrollment process for qualified individuals.

(a) * * *

(3) Issuers offering individual market QHPs must accept premium payments for a QHP on behalf of an enrollee that are made from the individual coverage HRA (as described in §

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146.123(b) of this subchapter) or qualified small employer health reimbursement arrangement (as described in section 9831(d)(2) of the Internal Revenue Code of 1986, as amended) in which the enrollee is enrolled.

* * * * *

PART 158 – ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

59. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg-18.

60. Section 158.103 is amended by adding the definition for “Prescription drug rebates and other price concessions” in alphabetical order to read as follows:

§ 158.103 Definitions.

* * * * *

Prescription drug rebates and other price concessions means all direct and indirect remuneration received or receivable by an issuer and entities providing pharmacy benefit management services to the issuer, related to the provision of a prescription drug covered by the issuer, regardless from whom the remuneration is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, vendor). Direct and indirect remuneration includes discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers, and excluding bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the

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manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

* * * * *

61. Section 158.240 is amended by adding paragraph (g) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(g) *Rebate prepayment and safe harbor.* An issuer may choose to pay a portion or all of its estimated rebate amount for a given MLR reporting year to enrollees in any form specified in § 158.241 prior to the rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and in advance of submitting the MLR report required in § 158.110 to the Secretary. Issuers that choose to prepay a portion or all of their rebates must do so for all eligible enrollees in a given state and market in a non-discriminatory manner. If, after submitting the MLR report required in § 158.110, an issuer determines that its rebate prepayment amount in a given state and market is at least 95 percent, but less than 100 percent, of the total rebate amount owed for the applicable MLR reporting year to enrollees in that state and market, the issuer may, without penalty or late payment interest under paragraph (f) of this section, provide the remaining rebate amount to those enrollees no later than the rebate deadlines in §§ 158.240(e) and 158.241(a)(2) applicable to the following MLR reporting year. If the total rebate owed to an enrollee for the MLR reporting year is above the *de minimis* threshold established in § 158.243(a), the issuer cannot treat the remaining rebate owed to an enrollee after prepayment as *de minimis*, even if the remaining rebate is below the *de minimis* threshold.

62. Section 158.241 is amended by revising paragraph (a)(2) to read as follows:

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§ 158.241 Form of rebate.

(a) * * *

(2) For each of the 2011, 2012, and 2013 MLR reporting years, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2014 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after September 30 following the MLR reporting year. If the amount of the rebate exceeds the premium due for October, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2020 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the monthly premium that is due no later than October 30 following the MLR reporting year. If the amount of the rebate exceeds the monthly premium, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

* * * * *

63. Subchapter E as added in final rule published on November 27, 2019 (84 FR 65524) and effective on January 1, 2021 is amended by adding part 184 to read as follows:

**PART 184 – PHARMACY BENEFIT MANAGER STANDARDS UNDER THE
AFFORDABLE CARE ACT**

Sec.

184.10 Basis and scope.

184.20 Definitions.

184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

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Authority: 42 U.S.C. 1302, 1320b-23.

§ 184.10 Basis and scope.

(a) *Basis.* (1) This part implements section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title XI of the Social Security Act.

(2) [Reserved]

(b) *Scope.* This part establishes standards for Pharmacy Benefit Managers that administer prescription drug benefits for health insurance issuers that offer Qualified Health Plans with respect to the offering of such plans.

§ 184.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Health insurance issuer has the meaning given to the term in § 144.103 of this subtitle.

Plan year has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 156.20 of this subchapter.

§ 184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, any entity that provides pharmacy benefits management services on behalf of a qualified health plan (QHP) issuer must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

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(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding *bona fide* service fees) that the pharmacy benefits manager (PBM) negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) *Bona fide* service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(b) *Limitations on disclosure.* Information disclosed by a PBM under this section shall not be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

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(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A PBM that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of section 1927(b)(3)(C) of the Act.

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CMS-9914-P

Dated: November 18, 2020.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: November 23, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

CMS-9914-P

Dated: November 25, 2020.

David J. Kautter,

Assistant Secretary (Tax Policy),

Department of the Treasury.

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