DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 600

Office of the Secretary

45 CFR Parts 153, 155, 156, and 158

[CMS–9888–P]

RIN 0938–AV41

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2026; and Basic Health Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule includes payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation (HHS–RADV) programs, as well as 2026 benefit year user fee rates for issuers that participate in the HHS-operated risk adjustment program and the 2026 benefit year user fee rates for issuers offering qualified health plans (QHPs) through Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal platform (SBE–FPs). This proposed rule also includes proposed requirements related to modifications to the calculation of the Basic Health Program (BHP) payment; and changes to the Initial Validation Audit (IVA) sampling approach and Second Validation Audit (SVA) pairwise means test for HHS–RADV. It also addresses HHS' authority to engage in compliance reviews of and take enforcement action against lead agents of insurance agencies for violations of HHS' Exchange standards and requirements; HHS' system suspension authority to address noncompliance by agents and brokers; an optional fixed-dollar premium payment threshold; proposed reconsideration standards for certification denials; proposed changes to the approach for conducting Essential Community Provider (ECP) certification reviews; a proposal to publicly share aggregated, summary-level Quality Improvement Strategy (QIS) information on an annual basis; and proposed revisions to the medical loss ratio (MLR) reporting and rebate requirements for qualifying issuers that meet certain standards.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by November 12, 2024.

ADDRESSES: In commenting, please refer to file code CMS–9888–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–9888–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9888–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:

Jeff Wu, (301) 492–4305, Rogelyn McLean, (301) 492–4229, Grace Bristol, (410) 786–8437, for general information.

Ayesha Anwar, (301) 492–4000, Joshua Paul, (301) 492–4347, or Debbie Noymer, (301) 448–3755 for matters related to HHS-operated risk adjustment.

Leanne Scott, (410) 786–1045 or Ayesha Anwar, (301) 492–4000 for matters related to HHS-operated risk adjustment data validation.

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

Brian Gubin, (410) 786–1659, for matters related to agent, broker, and web-broker guidelines.

Zarin Ahmed, (301) 492–4400, for matters related to enrollment of qualified individuals into QHPs and termination of Exchange enrollment or coverage for qualified individuals.

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

Preeti Hans, (301) 492–5144, for matters related to Quality Improvement Strategy.

Ken Buerger, (410) 786–1190, for matters related to certification standards for QHPs.

Nikolas Berkobien, (667) 290–9903, for matters related to standardized plan options, non-standardized plan option limits and exceptions, and financial requirements for issuers of QHPs on the FFEs.

Adelaide Balenger, (667) 414–0691, for matters related to the Actuarial Value Calculator.

Mary Evans, (470) 890–4113, for matters related to the Failure to File and Reconcile process.

Chris Truffer, (410) 786–1264, for matters related to the Basic Health Program (BHP) provision.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: 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 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. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a summary of not more than 100 words in length of this proposed rule, in plain language, may be found at *https://www.regulations.gov/.*

Intention of Future Rulemaking: HHS and the Departments of Labor and Treasury intend to issue a future notice of proposed rulemaking address the issues arising out of *HIV and Hepatitis Policy Institute et al.* v. *U.S. Department of Health and Human Services et al.,* Civil Action No. 22–2604 (D.D.C. Sept. 29, 2023), namely, the applicability of drug manufacturer support to the annual limitation on cost sharing.

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I. Executive Summary

We are proposing changes to the provisions and parameters implemented through prior rulemaking to implement the ACA.[1] These proposed requirements are published under the authority granted to the Secretary by the ACA and the PHS Act.[2] In this proposed rule, we are proposing changes related to some of the ACA provisions and parameters we previously implemented and are proposing new provisions. Our goal with these proposed requirements is providing quality, affordable coverage to consumers while minimizing administrative burden and ensuring program integrity. The changes proposed in this rule are also intended to help advance health equity, mitigate health disparities, and alleviate discrimination.

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 PHS Act to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the ACA.

Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.

Section 2718 of the PHS Act, as added by the ACA, generally requires health insurance issuers in the group and individual markets to submit an annual medical loss ratio (MLR) report to HHS and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

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

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary of HHS), cost-sharing limits, and AV requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Sections 1302(b)(4)(A) through (D) of the ACA establish that the Secretary must define EHB in a manner that: (1) reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

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

Section 1311(c) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(c)(1)(B) of the ACA requires, among the criteria for certification that the Secretary must establish by regulation, that QHPs ensure a sufficient choice of providers. Section 1311(d)(4)(A) of the ACA requires the Exchange to implement procedures for the certification, recertification, and decertification of health plans as QHPs, consistent with guidelines developed by the Secretary under section 1311(c) of the ACA. Section 1311(e)(1) of the ACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State. Section 1311(c)(6)(C) of the ACA directs the Secretary of HHS to

[1] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act,'' or ''ACA.''

[2] See sections 1301, 1302, 1311, 1312, 1313, 1321, 1331, and 1343 of the ACA and sections 2718 and 2792 of the PHS Act.

require an Exchange to provide for special enrollment periods and section 1311(c)(6)(D) of the ACA directs the Secretary of HHS to require an Exchange to provide for a monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

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

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

Section 1312(e) of the ACA provides the Secretary with the authority to establish procedures under which a State may allow agents or brokers to (1) enroll qualified individuals and qualified employers in QHPs offered through Exchanges and (2) assist individuals in applying for advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSRs) for QHPs sold through an Exchange.

Section 1312(f)(1)(B) of the ACA provides that an individual shall not be treated as a qualified individual for enrollment in a QHP if, at the time of enrollment, the individual is incarcerated, other than incarceration pending the disposition of charges.

Sections 1313 and 1321 of the ACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1313(a)(5)(A) of the ACA provides the Secretary with the authority to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the administration of the Exchanges. Section 1321 of the ACA provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the ACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the ACA, including such other requirements as the Secretary determines appropriate. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the public.

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

Section 1331 of the ACA provides States with an option to establish a Basic Health Program (BHP). In the States that elect to operate a BHP, the BHP makes affordable health benefits coverage available for individuals under age 65 with household incomes between 133 percent and 200 percent of the Federal poverty level (FPL) who are not otherwise eligible for Medicaid, the Children's Health Insurance Program (CHIP), or affordable employer-sponsored coverage, or for individuals whose income is equal to or below 200 percent of FPL but are lawfully present non-citizens ineligible for Medicaid. For those States that have expanded Medicaid coverage under section 1902(a)(10)(A)(i)(VIII) of the Social Security Act (the Act), the lower income threshold for BHP eligibility is effectively 138 percent of the FPL due to the application of a required 5 percent income disregard in determining the upper limits of Medicaid income eligibility (section 1902(e)(14)(I) of the Act).

Section 1343 of the ACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by charges collected from those issuers that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees. Section 1343(b) of the ACA provides that the Secretary, in consultation with States, shall establish criteria and methods to be used in carrying out the risk adjustment activities under this section. Consistent with section 1321(c) of the ACA, the Secretary is responsible for operating the HHS risk adjustment program in any State that fails to do so.[3]

Section 1401(a) of the ACA added section 36B to the Internal Revenue Code (the Code), which, among other things, requires that a taxpayer reconcile APTC for a year of coverage with the amount of the premium tax credit (PTC) the taxpayer is allowed for the year.

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

Section 1411(f) of the ACA requires the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Homeland Security, and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations. Section 1411(f)(1)(B) of the ACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for APTC and CSRs.

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

Section 1413 of the ACA directs the Secretary to establish, subject to minimum requirements, a streamlined enrollment process for enrollment in QHPs and all insurance affordability programs.

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals aged 30 and above qualify to enroll in

[3] In the 2014 through 2016 benefit years, HHS operated the risk adjustment program in every State and the District of Columbia, except Massachusetts. Beginning with the 2017 benefit year, HHS has operated the risk adjustment program in all 50 States and the District of Columbia.

catastrophic coverage under §§ 155.305(h) and 156.155(a)(5).

Section 1902(r)(2)(A) of the Act permits States to apply less restrictive methodologies than cash assistance program methodologies in determining eligibility for certain eligibility groups.

1. Premium Stabilization Programs

The premium stabilization programs refer to the risk adjustment, risk corridors, and reinsurance programs established by the ACA.[4] For past rulemaking, we refer readers to the following rules:

- In the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule), we implemented the premium stabilization programs.
- In the March 11, 2013 **Federal Register** (78 FR 15409) (2014 Payment Notice), we finalized the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs.
- In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the modification to the HHS risk adjustment methodology related to community rating States.
- In the November 6, 2013 **Federal Register** (78 FR 66653), we issued a correcting amendment to the 2014 Payment Notice to address how an enrollee's age for the risk score calculation would be determined under the HHS risk adjustment methodology.
- In the March 11, 2014 **Federal Register** (79 FR 13743) (2015 Payment Notice), we finalized the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and establish payment parameters in those programs.
- In the May 27, 2014 **Federal Register** (79 FR 30240), we announced the fiscal year 2015 sequestration rate for the HHS-operated risk adjustment program.
- In the February 27, 2015 **Federal Register** (80 FR 10749) (2016 Payment Notice), we finalized the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and establish the payment parameters in those programs.
- In the March 8, 2016 **Federal Register** (81 FR 12203) (2017 Payment Notice), we finalized the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and establish the payment parameters in those programs.
- In the December 22, 2016 **Federal Register** (81 FR 94058) (2018 Payment Notice), we finalized the benefit and payment parameters for the 2018 benefit year, added the high-cost risk pool parameters to the HHS risk adjustment methodology, incorporated prescription drug factors in the adult models, established enrollment duration factors for the adult models, and finalized policies related to the collection and use of enrollee-level External Data Gathering Environment (EDGE) data.
- In the April 17, 2018 **Federal Register** (83 FR 16930) (2019 Payment Notice), we finalized the benefit and payment parameters for the 2019 benefit year, created the State flexibility framework permitting States to request a reduction in risk adjustment State transfers calculated by HHS, and adopted a new error rate methodology for HHS–RADV adjustments to transfers.
- In the May 11, 2018 **Federal Register** (83 FR 21925), we issued a correction to the 2019 HHS risk adjustment coefficients in the 2019 Payment Notice.
- On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final HHS risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level EDGE data set.[5]
- In the July 30, 2018 **Federal Register** (83 FR 36456), we adopted the 2017 benefit year HHS risk adjustment methodology as established in the final rules issued in the March 23, 2012 (77 FR 17220 through 17252) and March 8, 2016 (81 FR 12204 through 12352) editions of the **Federal Register**. The final rule set forth an additional explanation of the rationale supporting the use of Statewide average premium in the State payment transfer formula for the 2017 benefit year, including the reasons why the program is operated by HHS in a budget-neutral manner. The final rule also permitted HHS to resume 2017 benefit year HHS 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 the publication of the final rule.
- In the December 10, 2018 **Federal Register** (83 FR 63419), we adopted the 2018 benefit year HHS risk adjustment methodology as established in the final rules issued in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. In the rule, we set forth an additional explanation of the rationale supporting the use of Statewide average premium in the State payment transfer formula for the 2018 benefit year, including the reasons why the program is operated by HHS in a budget-neutral manner.
- In the April 25, 2019 **Federal Register** (84 FR 17454) (2020 Payment Notice), we finalized the benefit and payment parameters for the 2020 benefit year, as well as the policies related to making the enrollee-level EDGE data available as a limited data set for research purposes and expanding the HHS uses of the enrollee-level EDGE data, approval of the request from Alabama to reduce HHS risk adjustment transfers by 50 percent in the small group market for the 2020 benefit year, and updates to HHS–RADV program requirements.
- On May 12, 2020, consistent with § 153.320(b)(1)(i), we issued the 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website.[6]
- In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized the benefit and payment parameters for the 2021 benefit year, as well as adopted updates to the HHS risk adjustment models' hierarchical condition categories (HCCs) to transition to the 10th revision of the International Statistical Classification of Diseases (ICD–10) codes, approved the request from Alabama to reduce HHS risk adjustment transfers by 50 percent in the small group market for the 2021 benefit year, and modified the outlier identification process under the HHS–RADV program.
- In the December 1, 2020 **Federal Register** (85 FR 76979) (Amendments to the HHS-Operated Risk Adjustment Data Validation Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program (2020 HHS–RADV Amendments Rule)), we adopted the creation and application of Super HCCs in the sorting step that assigns HCCs to failure rate groups, finalized a sliding scale adjustment in HHS–RADV error rate calculation, and added a constraint

[4] See section 1341 of the ACA (transitional reinsurance program), section 1342 of the ACA (risk corridors program), and section 1343 of the ACA (risk adjustment program).

[5] CMS. (2018). *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[6] CMS. (2020). Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

for negative error rate outliers with a negative error rate. We also established a transition from the prospective application of HHS–RADV adjustments to apply HHS–RADV results to risk scores from the same benefit year as that being audited.

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

• In the May 5, 2021 **Federal Register** (86 FR 24140) (part 2 of the 2022 Payment Notice), we finalized a subset of proposals from the December 4, 2020 **Federal Register** (85 FR 78572) (the 2022 Payment Notice proposed rule), including policy and regulatory revisions related to the HHS-operated risk adjustment program, finalization of the benefit and payment parameters for the 2022 benefit year, and approval of the request from Alabama to reduce HHS risk adjustment transfers by 50 percent in the individual and small group markets for the 2022 benefit year. In addition, this final rule established a revised schedule of collections for HHS–RADV and updated the provisions regulating second validation audit (SVA) and initial validation audit (IVA) entities.

• On July 19, 2021, consistent with § 153.320(b)(1)(i), we released Updated 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website, announcing some minor revisions to the 2022 benefit year final HHS risk adjustment adult model coefficients.[7]

• In the May 6, 2022 **Federal Register** (87 FR 27208) (2023 Payment Notice), we finalized revisions related to the HHS-operated risk adjustment program, including the benefit and payment parameters for the 2023 benefit year, HHS risk adjustment model recalibration, and policies related to the collection and extraction of enrollee-level EDGE data. We also finalized the adoption of the interacted HCC count specification for the adult and child models, along with modified enrollment duration factors for the adult models, beginning with the 2023 benefit year.[8] We also repealed the ability for States, other than prior participants, to request a reduction in HHS risk adjustment State transfers starting with the 2024 benefit year. In addition, we approved a 25 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama's individual market and a 10 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama's small group market. We also finalized further refinements to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year.

• In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we finalized the benefit and payment parameters for the 2024 benefit year, amended the EDGE discrepancy materiality threshold and data collection requirements, and reduced the risk adjustment user fee. For the 2024 benefit year, we approved 50 percent reductions to HHS risk adjustment transfers for Alabama's individual and small group markets, and repealed prior participant States' ability to request reductions of their risk adjustment transfers for the 2025 benefit year and beyond. We finalized several refinements to HHS–RADV program requirements, such as shortening the window to confirm SVA findings or file a discrepancy report, changing the HHS–RADV materiality threshold for random and targeted sampling, and no longer exempting exiting issuers from adjustments to risk scores and HHS risk adjustment transfers when they are negative error rate outliers. We also announced the discontinuance of the Lifelong Permanent Condition List (LLPC) and Non-EDGE Claims (NEC) in HHS–RADV beginning with the 2022 benefit year.

• In the April 15, 2024 **Federal Register** (89 FR 26218) (2025 Payment Notice), we finalized the benefit and payment parameters for the 2025 benefit year, including the 2025 risk adjustment models and updated the adjustment factors for the receipt of CSRs for the American Indian and Alaska Native (AI/AN) subpopulation who are enrolled in zero and limited cost-sharing plans to improve prediction in the HHS risk adjustment models. In addition, we finalized that in certain cases, we may require a corrective action plan (CAP) to address an observation identified in an HHS risk adjustment program audit.

2. Program Integrity

We have finalized program integrity standards related to the Exchanges and premium stabilization programs in two rules: the ''first Program Integrity Rule'' issued in the August 30, 2013 **Federal Register** (78 FR 54069), and the ''second Program Integrity Rule'' issued in the October 30, 2013 **Federal Register** (78 FR 65045). We also refer readers to the 2019 Patient Protection and Affordable Care Act; Exchange Program Integrity final rule (2019 Program Integrity Rule) issued in the December 27, 2019 **Federal Register** (84 FR 71674).

In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we finalized a policy to implement improper payment pre-testing and assessment (IPPTA) requirements for State Exchanges to ensure adherence to the Payment Integrity Information Act of 2019. In addition, we finalized allowing additional time for HHS to review evidence submitted by agents and brokers to rebut allegations pertaining to Exchange agreement suspensions or terminations. We also introduced consent and eligibility application documentation requirements for agents, brokers, and web-brokers that assist Exchange consumers in FFE and SBE–FP States.

3. Market Rules

In the February 27, 2013 **Federal Register** (78 FR 13406), we issued the health insurance market rules, including provisions related to the single risk pool. We amended requirements related to index rates under the single risk pool provision in a final rule issued in the July 2, 2013 **Federal Register** (78 FR 39870). In the October 30, 2013 **Federal Register** (78 FR 65046), we clarified when issuers may establish and update premium rates. In the March 8, 2016 **Federal Register** (81 FR 12203), we clarified single risk pool provisions related to student health insurance coverage. We finalized minor adjustments to the single risk pool regulations in the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058).

4. Exchanges

We issued a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. In the March 27, 2012 **Federal Register** (77 FR 18310) (Exchange Establishment Rule), we implemented the Affordable Insurance Exchanges (Exchanges), consistent with title I of the ACA, to provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. This

[7] CMS. (2021). 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients. *https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf.*

[8] CMS (2022). 2023 Benefit Year Final HHS Risk Adjustment Model Coefficients. *https://www.cms.gov/files/document/2023-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf.*

included implementation of components of the Exchanges and standards for eligibility for Exchanges, as well as network adequacy and essential community provider (ECP) certification standards.

In the August 17, 2011 **Federal Register** (76 FR 51201), we issued a proposed rule regarding eligibility determinations, including the regulatory requirement to verify incarceration status. In the March 27, 2012 **Federal Register** (77 FR 18310) we finalized the regulatory requirement to verify incarceration attestation using an approved electronic data source that is current and accurate, and to resolve the inconsistency when attestations are not reasonably compatible with information in an approved data source. We also established requirements regarding accessible communications for individuals with disabilities and those with LEP.

In the 2014 Payment Notice and the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, issued 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, issued in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In the 2016 Payment Notice, we also set forth the ECP certification standard at § 156.235, with revisions in the 2017 Payment Notice in the March 8, 2016 **Federal Register** (81 FR 12203) and the 2018 Payment Notice in the December 22, 2016 **Federal Register** (81 FR 94058).

In the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058), we set forth the standards for the request for reconsideration of denial of certification specific to the FFEs at § 155.1090.

In an interim final rule, issued in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058).

In the Market Stabilization final rule, issued in the April 18, 2017 **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice, issued 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 2020 Payment Notice established a new special enrollment period.

In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized revisions to the parameters of special enrollment periods and the quality rating information display standards for State Exchanges and amended the periodic data matching requirements.

In the January 19, 2021 **Federal Register** (86 FR 6138) (part 1 of the 2022 Payment Notice), we finalized only a subset of the proposals in the 2022 Payment Notice proposed rule. In the May 5, 2021 **Federal Register** (86 FR 24140), we issued part 2 of the 2022 Payment Notice. In part 3 of the 2022 Payment Notice, issued in the September 27, 2021 **Federal Register** (86 FR 53412), in conjunction with the Department of the Treasury, we finalized amendments to certain policies in part 1 of the 2022 Payment Notice.

In the May 6, 2022 **Federal Register** (87 FR 27208), we finalized changes to maintain the user fee rate for issuers offering plans through the FFEs and maintain the user fee rate for issuers offering plans through the SBE–FPs for the 2023 benefit year. We also finalized various policies to address certain agent, broker, and web-broker practices and conduct. We also finalized updates to the requirement that all Exchanges conduct special enrollment period verifications.

In the 2024 Payment Notice, issued in the April 27, 2023 **Federal Register** (88 FR 25740), we revised Exchange Blueprint approval timelines, lowered the user fee rate for QHPs in the FFEs and SBE–FPs, and amended re-enrollment hierarchies for enrollees. We also finalized policies to update FFE and SBE–FP standardized plan options; reduced the risk of plan choice overload on the FFEs and SBE–FPs by limiting the number of non-standardized plan options that issuers may offer through Exchanges on the Federal platform to four for PY 2024 and to two for PY 2025 and subsequent years; and ensure correct QHP information. In addition, we amended coverage effective date rules, lengthened the special enrollment period from 60 to 90 days for those who lose Medicaid coverage, and prohibited QHPs on FFEs and SBE–FPs from terminating coverage mid-year for dependent children who reach the applicable maximum age. We also finalized policies on verifying consumer income and permitting door-to-door assisters to solicit consumers. To ensure provider network adequacy, we finalized provider network and ECP policies for QHPs. We revised the failure to file and reconcile process to ensure enrollees would not lose APTC eligibility until they or their tax filer failed to file their Federal income taxes and reconcile APTC for two consecutive tax years.

In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we required a State seeking to operate a State Exchange to first operate an SBE–FP for at least one plan year, revised Exchange Blueprint requirements for States transitioning to a State Exchange, established additional minimum standards for Exchange call center operations, required an Exchange to operate a centralized eligibility and enrollment platform on its website, and finalized various policies for web-brokers and direct enrollment entities. In addition, we required State Exchanges and State Medicaid agencies to remit payment to HHS for their use of certain income data, amended re-enrollment hierarchies for enrollees enrolled in catastrophic coverage, revised the parameters around a State Exchange adopting an alternative open enrollment period, and extended the availability of a special enrollment period for APTC-eligible qualified individuals with a projected annual household income no greater than 150 percent of the Federal Poverty Level (FPL). To ensure provider network adequacy in State Exchanges and SBE–FPs, we finalized provider network adequacy policies applicable to such Exchanges for PY 2026 and subsequent plan years. We also further lowered the user fee rate for QHPs in the FFEs and SBE–FPs. In addition, we finalized the policy to maintain FFE and SBE–FP standardized plan option metal levels from the 2024 Payment Notice and finalized an exceptions process to the limitation on non-standardized plan options in FFEs and SBE–FPs. We also finalized the requirement for Exchanges to provide notification to enrollees or their tax filers who have failed to file their Federal income taxes and reconcile APTC for one tax year.

5. Essential Health Benefits

We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was issued in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule). We established at § 156.135(a) that AV is generally to be calculated using the AV Calculator developed and made available by HHS for a given benefit year. In the 2015 Payment Notice (79 FR 13743), we established at § 156.135(g) provisions

for updating the AV Calculator in future plan years. In the 2017 Payment Notice (81 FR 12349), we amended the provisions at § 156.135(g) to allow for additional flexibility in our approach and options for updating of the AV Calculator.

In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we revised § 155.170(a) to codify that benefits covered in a State's EHB-benchmark plan are not considered in addition to EHB, even if they had been required by State action taking place after December 31, 2011, other than for purposes of compliance with Federal requirements. We finalized three revisions to the standards for State selection of EHB-benchmark plans for benefit years beginning on or after January 1, 2026: we revised the typicality standard at § 156.111 for States to demonstrate that their new EHB-benchmark plan provides a scope of benefits that is equal to that of a typical employer plan in the State and removed the generosity standard; removed the requirement for States to submit a formulary drug list as part of their application unless they are changing their prescription drug EHBs; and consolidated the options for States to change their EHB-benchmark plans. We also removed the regulatory prohibition at § 156.115(d) on issuers from including routine non-pediatric dental services as an EHB beginning with PY 2027. In addition, we revised § 156.122 to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB. We also stated that HHS and the Departments of Labor and the Treasury intend to propose rulemaking that would align the standards applicable to large group market health plans and self-insured group health plans with those applicable to individual and small group market plans, so that all group health plans and health insurance coverage subject to sections 2711 and 2707(b) of the PHS Act, as applicable, would be required to treat prescription drugs covered by the plan or coverage in excess of the applicable EHB-benchmark plan as EHB for purposes of the prohibition of lifetime and annual limits and the annual limitation on cost sharing, which would further strengthen the consumer protections in the ACA.

6. Medical Loss Ratio (MLR)

We issued a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297) and issued an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74864). A final rule with a 30-day comment period was issued in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was issued in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was issued in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules issued in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164), the May 5, 2021 **Federal Register** (86 FR 24140), and the May 6, 2022 **Federal Register** (87 FR 27208), and an interim final rule that was issued in the September 2, 2020 **Federal Register** (85 FR 54820).

7. Quality Improvement Strategy

We issued regulations in § 155.200(d) to direct Exchanges to evaluate quality improvement strategies, and § 156.200(b) to direct QHP issuers to implement and report on a quality improvement strategy or strategies consistent with section 1311(g) standards as QHP certification criteria for participation in an Exchange. In the 2016 Payment Notice, issued in the February 27, 2015 **Federal Register** (80 FR 10749), we finalized regulations at § 156.1130 to establish standards and the associated timeframe for QHP issuers to submit the necessary information to implement quality improvement strategy standards for QHPs offered through an Exchange.

8. Basic Health Program

In the March 12, 2014, **Federal Register** (79 FR 14111), we issued a final rule entitled the ''Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity'' (hereinafter referred to as the BHP final rule) implementing section 1331 of the ACA, which governs the establishment of BHPs. The BHP final rule established the standards for State and Federal administration of BHPs, including provisions regarding eligibility and enrollment, benefits, cost-sharing requirements and oversight activities. In the BHP final rule, we specified that the BHP Payment Notice process would include the annual publication of both a proposed and final BHP payment methodology.

On October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury (the Departments) with a legal opinion [9] indicating that the permanent appropriation at 31 U.S.C. 1324, from which the Departments had historically drawn funds to make CSR payments, cannot be used to fund CSR payments to insurers. In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides for an appropriation. As a result of this opinion, CMS discontinued CSR payments to issuers in the States operating a BHP (that is, New York and Minnesota). The States then sued the Secretary for declaratory and injunctive relief in the United States District Court for the Southern District of New York.[10] On May 2, 2018, the parties filed a stipulation requesting a stay of the litigation so that HHS could issue an administrative order revising the 2018 BHP payment methodology. After consideration of the States' comments on the administrative order revising the payment methodology, we issued a Final Administrative Order on August 24, 2018 (Final Administrative Order) setting forth the payment methodology that would apply to the 2018 BHP program year.

In the November 5, 2019 **Federal Register** (84 FR 59529) (hereinafter referred to as the November 2019 final BHP Payment Notice), we finalized the payment methodologies for BHP program years 2019 and 2020.[11] The 2019 payment methodology is the same payment methodology described in the Final Administrative Order. The 2020 payment methodology is the same methodology as the 2019 payment methodology with one additional adjustment to account for the impact of individuals selecting different metal tier level plans in the Exchange, referred to as the Metal Tier Selection Factor

[9] Sessions, J. (2017, Oct. 11). *Legal Opinion Re: Payments to Issuers for Cost Sharing Reductions (CSRs).* Office of the Attorney General. *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.*

[10] See *New York* v. *U.S. Dep't of Health & Human Servs.,* No. 18–cv–00683 (RJS) (S.D.N.Y. filed Jan. 26, 2018).

[11] BHP program year means a calendar year for which a standard health plan provides coverage for BHP enrollees. *See* 42 CFR 600.5.

(MTSF).[12] In the August 13, 2020 **Federal Register** (85 FR 49264) (hereinafter referred to as the August 2020 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2021. The 2021 payment methodology is the same methodology as the 2020 payment methodology, with one adjustment to the income reconciliation factor (IRF). In the July 7, 2021 **Federal Register** (86 FR 35615) (hereinafter referred to as the July 2021 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2022. The 2022 payment methodology is the same as the 2021 payment methodology, with the exception of the removal of the Metal Tier Selection Factor.

In the December 20, 2022 **Federal Register** (87 FR 77722) (hereafter referred to as the 2023 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2023. The 2023 payment methodology is the same as the 2022 payment methodology, except for the addition of a factor to account for a State operating a BHP and implementing an approved State Innovation Waiver under section 1332 of the ACA; this is the section 1332 waiver factor (WF). In the 2023 final BHP Payment Notice (87 FR 77723), we also revised the schedule for issuance of payment notices and allowed payment notices to be effective for 1 or multiple program years, as determined by and subject to the direction of the Secretary, beginning with the 2023 payment methodology. In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we finalized that States may start BHP applicants' effective date of eligibility on the first day of the month following the date of application. In addition, we finalized that, subject to HHS approval, a State may establish its own effective date of eligibility for enrollment policy.

B. Summary of Major Provisions

The regulations outlined in this proposed rule would be codified in 42 CFR part 600 and 45 CFR parts 153, 155, 156, and 158.

1. 42 CFR Part 600

We are proposing changes to the methodology regarding the premium adjustment factor (PAF), which is used to calculate the adjusted reference premium (ARP) for BHP payment. We propose maintaining the PAF value at 1.188 for States that have fully implemented BHP and are using Second Lowest Cost Silver Plan (SLCSP) premiums from a year in which BHP was fully implemented. As previously clarified, for States in their first year of implementing BHP and choosing to use prior year SLCSP premiums to determine BHP payment, the PAF value would be set to 1.00. We propose that if a State is using SLCSP premiums from a year in which BHP was not fully implemented, the PAF is calculated by determining the CSR adjustment that QHP issuers included in the SLCSP premiums, reporting the CSR adjustments for the SLCSP for each region in the State to CMS, and then CMS calculating the PAF as 1.20 divided by 1 plus the adjustment. Additionally, we are proposing a technical clarification for BHP payment rates in cases of multiple SLCSP premiums in an area.

2. 45 CFR Part 153

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2025, the HHS-operated risk adjustment program is subject to the fiscal year 2025 sequestration.[13] Therefore, the HHS-operated risk adjustment program will sequester payments made from fiscal year 2025 resources (that is, funds collected during the 2025 fiscal year) at a rate of 5.7 percent.

We propose to recalibrate the 2026 benefit year HHS risk adjustment models using the 2020, 2021, and 2022 benefit year enrollee-level EDGE data. Starting with the 2026 benefit year, we propose to begin phasing out the market pricing adjustment to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models (see, for example, 84 FR 17463 through 17466). We also are proposing to incorporate pre-exposure prophylaxis (PrEP) as a separate, new type of factor called an Affiliated Cost Factor (ACF) in the HHS risk adjustment adult and child models starting with the 2026 benefit year. We also request information on whether the HHS-operated risk adjustment program should take into account the time value of money for the collection and remittance of State transfers that occur 8 to 10 months after the conclusion of the benefit year. We also propose a risk adjustment user fee for the 2026 benefit year of $0.18 per member per month (PMPM).

Beginning with the 2025 benefit year of HHS–RADV, we propose to exclude enrollees without HCCs, which includes enrollees with only prescription drug categories (RXCs), from the IVA sample, remove the Finite Population Correction (FPC) from the IVA sampling methodology, and replace the source of the Neyman allocation data used for HHS–RADV sampling with the most recent 3 years of consecutive HHS–RADV data. In addition, beginning with the 2024 benefit year of HHS–RADV, we propose to modify the SVA pairwise means test, which tests for statistical differences between the IVA and SVA results, to use a bootstrapped 90 percent confidence interval methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees.

3. 45 CFR Part 155

We seek comment on how assisters who perform their assister duties in a hospital and hospital system may, within the bounds of the statute, refer consumers to programs designed to reduce medical debt.

We address our authority to investigate and undertake compliance reviews and enforcement actions in response to misconduct or noncompliance with applicable agent, broker, and web-broker Exchange requirements or standards occurring at the insurance agency level and how we intend to hold lead agents of insurance agencies accountable for such misconduct or noncompliance.

We propose to revise § 155.220(k)(3) to reflect our authority to suspend an agent's or broker's ability to transact information with the Exchange in instances where HHS discovers circumstances that pose unacceptable risk to accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.

We propose to update the Model Consent Form that agents, brokers, and web-brokers can use to obtain and document consumer consent.[14] The

[12] ''Metal tiers'' refer to the different actuarial value plan levels offered on the Exchanges. Bronze-level plans generally must provide 60 percent actuarial value; silver-level 70 percent actuarial value; gold-level 80 percent actuarial value; and platinum-level 90 percent actuarial value. See 45 CFR 156.140.

[13] OMB. (2024). OMB Report to *the* Congress on *the* BBEDCA *251A* Sequestration for *Fiscal Year* 2025. *https://www.whitehouse.gov/wp-content/uploads/2024/03/BBEDCA_251A_Sequestration_Report_FY2025.pdf.*

[14] CMS. (2022, December 14). *CMS Model Consent Form for Marketplace Agents and Brokers.* PRA package (CMS–10840, OMB 0938–1438).

Continued

updates would expand the resource to include a standardized form that agents, brokers, and web-brokers can use to document the consumer's review and confirmation of the accuracy of information in their Exchange eligibility application, which is a new standard of conduct that was also implemented as part of the 2024 Payment Notice (88 FR 25809 through 25814). The proposed updates would also add scripts that agents, brokers, and web-brokers could utilize to meet the consumer consent and eligibility application review requirements finalized in the 2024 Payment Notice via an audio recording. We are not proposing any regulatory text changes since the use of the updated Model Consent Form would not be mandatory.

We propose to amend § 155.305(f)(4) to require Exchanges to provide notice to consumers and tax filers who have failed to file and reconcile their APTC for 2 consecutive years.

We propose to add § 155.400(d)(1) to codify HHS' guidance that requires that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, State Exchanges must review and resolve the State Exchange issuer's enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.

We propose to revise § 155.400(g) to allow issuers to adopt a fixed-dollar payment threshold of $5 or less, adjusted for inflation, under which issuers would not be required to trigger a grace period or terminate enrollment for enrollees who fail to pay the full amount of their portion of premium owed. We propose to limit application of this fixed-dollar payment threshold to premium payments after coverage is effectuated. Issuers would be required to apply the fixed-dollar threshold uniformly to all enrollees and without regard to their health status. Issuers would be allowed to apply either the fixed-dollar payment threshold or one of two percentage-based thresholds (one of which is currently permitted under § 155.400(g), but which we propose to modify).

https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf.

We propose revisions to § 155.505(b) to codify an option for application filers to file appeals on behalf of applicants and enrollees on the application filer's Exchange application, as this would streamline the appeals process and ensure operational consistency between the FFEs and the HHS appeals entity or State Exchange appeals entity.

We propose to amend § 155.1000 to state explicitly that an Exchange may deny certification to any plan that does not meet the general certification criteria at § 155.1000(c). We also propose to amend § 155.1090 with refinements to the standards for a request for the reconsideration of a denial of certification specific to the FFEs.

We propose that in addition to collecting the information and data currently provided by Exchanges under § 155.1200 to monitor performance and compliance, we would use the information and data that Exchanges submit to increase transparency into Exchange operations and to promote program improvements. We anticipate publicly releasing the Exchanges annual State-based Marketplace Annual Reporting Tools (SMARTs), programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment (OE) Data Reports. We are seeking input on how to best display these data points and how to best develop a performance measurement tool to assess Exchange quality and consumer experience.

4. 45 CFR Part 156

We solicit comments on reducing the risk of issuer insolvencies adversely impacting the integrity of the FFEs.

We propose 2026 benefit year FFE and SBE–FP user fee rates of 2.5 percent and 2.0 percent of total monthly premiums, respectively. However, if the enhanced PTC subsidies as currently enacted [15] or at a higher level are extended through the 2026 benefit year by March 31, 2025, we propose a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE–FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule.

We affirm that certain CSR loading practices that are permitted by State regulators are permissible under Federal law to the extent that they are reasonable and actuarially justified. We seek comment on whether we should codify this guidance at § 156.80(d).

We intend to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator. Under this approach, for a plan year, we would only release a single, final version of the AV Calculator. We would also solicit public comments on the AV Calculator for a plan year generally but would only plan to incorporate this feedback into the development and release of the following plan year's AV Calculator.

We propose to make minor updates to the standardized plan option designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis range* for each metal level and to maintain a high degree of continuity with the approaches to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices. In addition, we propose to amend § 156.201 to require issuers that offer multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

We propose to amend § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since these requirements were introduced to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage categories under the non-standardized plan option limit in accordance with § 156.202(c)(1) through (3).

We propose to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions, beginning in PY 2026.

We propose to share aggregated, summary-level QIS information publicly on an annual basis beginning on January 1, 2026, with information QHP issuers submit during the PY 2025 QHP Application Period.

We propose to amend § 156.1220(a) to introduce a new materiality threshold for HHS–RADV appeals, such that HHS would rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal when the impact of that appeal to the filer's HHS–RADV adjustments to State transfers is greater than or equal to $10,000.

5. 45 CFR Part 158

We propose to amend § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to

[15] ARP, Public Law 117–2 (2021). These enhanced subsidies were extended under the IRA, Public Law 117–169 (2022) and are scheduled to expire after the 2025 calendar year.

the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year (MLR reports due in 2027). We propose that for qualifying issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium, such that these net receipts would impact the MLR denominator rather than MLR numerator. We propose to amend § 158.103 to add a definition of ''qualifying issuer.''

We also propose amendments to § 158.240(c) to add an illustrative example of how qualifying issuers would calculate the amount of rebate owed to each enrollee to accurately reflect how such issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers, as well as a conforming amendment to clarify that the current illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers.

III. Provisions of the Proposed Regulations

A. 42 CFR Part 600 BHP Methodology Regarding the Value of the Premium Adjustment Factor (PAF)

1. Overview of the Payment Methodology and Calculation of the Payment Amount

Section 1331(d)(3) of the ACA directs the Secretary to consider several factors when determining the Federal BHP payment amount, which, as specified in the statute, must equal 95 percent of the value of the PTC under section 36B of the Code and CSRs under section 1402 of the ACA that would have been paid on behalf of BHP enrollees had they enrolled in a QHP through an Exchange. Thus, the BHP payment methodology is designed to calculate the PTC and CSRs as consistently as possible and in general alignment with the methodology used by Exchanges to calculate advance payments of the PTC (APTC) and CSRs, and the methodology used to reconcile APTC with the amount of the PTC allowed for the tax year under section 36B of the Code. In accordance with section 1331(d)(3)(A)(iii) of the ACA, the final payment methodology must be certified by the Chief Actuary of CMS, in consultation with the Office of Tax Analysis (OTA) of the Department of the Treasury, as having met the requirements of section 1331(d)(3)(A)(ii) of the ACA.

Section 1331(d)(3)(A)(ii) of the ACA specifies that the payment determination shall take into account all relevant factors necessary to determine the value of the PTC and CSRs that would have been paid on behalf of eligible individuals, including but not limited to, the age and income of the enrollee, whether the enrollment is for self-only or family coverage, geographic differences in average spending for health care across rating areas, the health status of the enrollee for purposes of determining risk adjustment payments and reinsurance payments that would have been made if the enrollee had enrolled in a QHP through an Exchange, and whether any reconciliation of APTC and CSR would have occurred if the enrollee had been enrolled. Under all previous payment methodologies, the total Federal BHP payment amount has been calculated using multiple rate cells in each BHP State. Each rate cell represents a unique combination of age range (if applicable), geographic area, coverage category (for example, self-only or two-adult coverage through the BHP), household size, and income range as a percentage of FPL, and there is a distinct rate cell for individuals in each coverage category within a particular age range who reside in a specific geographic area and are in households of the same size and income range. The BHP payment rates developed are also consistent with the State's rules on age rating. Thus, in the case of a State that does not use age as a rating factor on an Exchange, the BHP payment rates would not vary by age.

Under the methodology finalized in the July 2021 final BHP Payment Notice, the rate for each rate cell is calculated in 2 parts. The first part is equal to 95 percent of the estimated PTC that would have been allowed if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. The second part is equal to 95 percent of the estimated CSR payment that would have been made if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. These two parts are added together and the total rate for that rate cell would be equal to the sum of the PTC and CSR rates. As noted in the July 2021 final BHP Payment Notice, we currently assign a value of zero to the CSR portion of the BHP payment rate calculation, because there is presently no available appropriation from which we can make the CSR portion of any BHP payment.

The 2023 final BHP Payment Notice provides a detailed description of the structure of the BHP payments, including the equations, factors, and the values of the factors used to calculate the BHP payments. We are proposing one change to the methodology regarding the premium adjustment factor (PAF).

The PAF is used to calculate the adjusted reference premium (ARP) that is used to calculate the BHP payment. The adjusted reference premium (ARP) is used to calculate the estimated PTC that would be allowed if BHP-eligible individuals enrolled in QHPs through an Exchange and is based on the premiums for the applicable second lowest cost silver plan during the applicable plan year. The PAF considers the premium increases in other States that took effect after we discontinued payments to issuers for CSRs provided to enrollees in QHPs offered through Exchanges. Despite the discontinuance of Federal payments for CSRs, QHP issuers are required to provide CSRs to eligible enrollees. As a result, many QHP issuers increased the silver-level plan premiums to account for those additional costs; these premium adjustments and how they were applied (for example, to only silver-level plans or to all metal tier plans) varied across States. For the States operating BHPs in 2018, the increases in premiums were relatively minor, because the majority of enrollees eligible for CSRs (and all who were eligible for the largest CSRs) were enrolled in the BHP and not in QHPs on the Exchanges, and therefore issuers in BHP States did not significantly raise premiums to cover costs related to HHS not making CSR payments.

In the Final Administrative Order and the 2019 through 2023 final BHP Payment Notices, we incorporated the PAF into the BHP payment methodologies to capture the impact of how other States responded to HHS ceasing to make CSR payments.[16] We also reserved the right that in the case an appropriation for CSR payments is made for a future year, we would determine whether and how to modify the PAF in the payment methodology.

Under the Final Administrative Order, we calculated the PAF by using information sought from QHP issuers in each State and the District of Columbia and determined the premium adjustment that the responding QHP issuers made to each silver level plan in 2018 to account for the discontinuation of CSR payments to QHP issuers. Based on the data collected, we estimated the median adjustment for silver level QHPs nationwide (excluding those in the two BHP States). To the extent that QHP issuers made no adjustment (or the adjustment was zero), this was counted as zero in determining the median

[16] *https://www.medicaid.gov/sites/default/files/2019-11/final-admin-order-2018-revised-payment-methodology.pdf.*

adjustment made to all silver level QHPs nationwide. If the amount of the adjustment was unknown—or we determined that it should be excluded for methodological reasons (for example, the adjustment was negative, an outlier, or unreasonable)—then we did not count the adjustment towards determining the median adjustment.[17] The median adjustment for silver level QHPs is referred to as the nationwide median adjustment.

For each of the two BHP States, we determined the median premium adjustment for all silver level QHPs in that State, which we refer to as the State median adjustment. The PAF for each BHP State equaled one plus the nationwide median adjustment divided by one plus the State median adjustment for the BHP State. In other words,

PAF = (1 + Nationwide Median Adjustment) ÷ (1 + State Median Adjustment).

To determine the PAF described above, we sought to collect QHP information from QHP issuers in each State and the District of Columbia to determine the premium adjustment those issuers made to each silver level plan offered through the Exchange in 2018 to account for the end of CSR payments. Specifically, we sought information showing the percentage change that QHP issuers made to the premium for each of their silver level plans to cover benefit expenditures associated with the CSRs, given the lack of CSR payments in 2018. This percentage change was a portion of the overall premium increase from 2017 to 2018.

According to our 2018 records, there were 1,233 silver-level QHPs operating on Exchanges in 2018. Of these 1,233 QHPs, 318 QHPs (25.8 percent) responded to our request for the percentage adjustment applied to silver-level QHP premiums in 2018 to account for the discontinuance of HHS making CSR payments. These 318 QHPs operated in 26 different States, with 10 of those States running State Exchanges (while we requested information only from QHP issuers in States serviced by an FFE, many of those issuers also had QHPs in State Exchanges and submitted information for those States as well). Thirteen of these 318 QHPs were in New York (and none were in Minnesota). Excluding these 13 QHPs from the analysis, the nationwide median adjustment was 20.0 percent. Of the 13 QHPs in New York that responded, the State median adjustment was 1.0 percent. We believed that this was an appropriate adjustment for QHPs in Minnesota, as well, based on the observed changes in New York's QHP premiums in response to the discontinuance of CSR payments (and the operation of the BHP in that State) and our analysis of expected QHP premium adjustments for States with BHPs. We calculated the proposed PAF as (1 + 20%) ÷ (1 + 1%) (or 1.20/1.01), which results in a value of 1.188.

We set the value of the PAF to 1.188 for all program years for 2018 through 2024, with limited exceptions.[18] We believe that this value for the PAF continues to reasonably account for the increase in silver-level premiums experienced in non-BHP States that took effect after the discontinuance of the CSR payments.

Starting in 2023, we made one limited exception in setting the value of the PAF as part of the 2023 final BHP Payment Notice.[19] In the case of a State in the first year of implementing a BHP, if the State chooses to use prior year second lowest cost silver plan (SLCSP) premiums to determine the BHP payment (for example, the 2025 premiums for the 2026 program year), we set the value of the PAF to 1.00. In this case, we believe that adjustment to the QHP premiums to account for the discontinuation of CSR payments would be included fully in the prior year premiums, and no further adjustment would be necessary.

We propose to make a change to the calculation of the PAF starting in program year 2026. There are cases in which a State may not have fully implemented BHP for a full program year. For example, a State may operate BHP for only a portion of the year (in other words, less than 12 months); there may be other such cases in which a State would be deemed to have partially implemented BHP for a program year.

For a State that initially only partially implemented BHP, it is likely that, in the year (or years) when the BHP is only partially implemented, the percentage adjustment to the premiums for the program year to account for the discontinuation of CSR payments may be significantly higher than the 1 percent adjustment we determined for BHP States in 2018. In these cases, it is probable that QHP issuers would include a larger premium adjustment (that is, greater than 1 percent) because more individuals would be eligible for CSRs (and individuals eligible for relatively larger CSRs) would be enrolled in a QHP on the Exchange, for part or all of the initial implementation year. If premiums with a larger CSR adjustment are used as a basis for calculating the BHP payments and the current value of the PAF (1.188) is used, it is likely that this would ''double count'' a portion of the adjustment and lead to an effective CSR adjustment over 20 percent.

For example, assume a State implements BHP for only 6 months in a program year. As a result, QHP issuers may include a 10 percent adjustment to the premiums to account for the discontinuation of the CSR for the portion of the year when CSR eligible individuals would have QHP coverage. The issuers would be liable for roughly half of the CSR amounts they would have had to provide if there was no BHP in place. Under the previous BHP payment methodology, if these premiums that already partially account for CSRs are used to calculate the BHP payment, we would increase the reference premium by 18.8 percent for the PAF, leading to an effective increase of 30.68 percent (1.188 multiplied by 1.10 minus 1). This is significantly larger than the 20 percent adjustment we determined as the basis for the PAF for States that have operated their BHP for more than two full program years.

Under the Secretary's general authority to account for all relevant factors necessary to determine the value of the premium and cost-sharing reductions that would have been provided to eligible individuals now enrolled in BHP coverage[20] and to avoid such an overpayment, we propose the following changes to the PAF:

(1) If a State has fully implemented BHP and is using SLSCP premiums for a year in which the BHP was fully implemented, then the value of the PAF would remain 1.188, as described above.

(2) If a State is in the first year of implementing a BHP and the State chooses to use prior year SLCSP premiums to determine the BHP payment (for example, the 2025 premiums for the 2026 program year), we set the value of the PAF to 1.00. This is the same approach described in the 2023 final BHP Payment Notice.

(3) If a State is using SLCSP premiums from a year in which BHP was not fully implemented, then the PAF is calculated as follows:

First, the State must determine the CSR adjustment that QHP issuers included in the SLSCP premiums for individual

[17] Some examples of outliers or unreasonable adjustments include (but are not limited to) values over 100 percent (implying the premiums doubled or more because of the adjustment), values more than double the otherwise highest adjustment, or non-numerical entries.

[18] 87 FR 77731, 77737.

[19] Id. at 77732.

[20] Section 1331(d)(3)(A)(ii) of the PHS Act.

market Exchange plans. The State should identify the SLSCP in each region, as defined for the Exchange. For each SLSCP, the State should determine the CSR adjustment that the QHP issuer included in the premium. This may be done by (1) reviewing any materials submitted by the QHP issuer describing the calculation of the premium; or (2) requesting that the QHP issuer provide the adjustment, or an estimate of the adjustment used in calculating the premium. Second, the State should report the CSR adjustments for the SLCSP for individual market Exchange plans for each region in the State to CMS. Third, CMS will take this percentage adjustment and calculate the PAF as 1.20 divided by 1 plus the adjustment. For example, if the percentage adjustment for the CSR is 5 percent, the PAF would be (1.20 ÷ 1.05), or 1.143. The maximum value of the PAF would be 1.188, and the minimum value of the PAF would be 1.00.

This approach would apply based on the premium year, not necessarily the program year. If the State has fully implemented BHP but is using the prior year premiums and BHP was not fully implemented in that year, this modified approach would still apply. For example, if a State partially implemented BHP in 2026 and fully implemented BHP in 2027, when determining the BHP payments for 2027, we would then use 1.188 for the value of the PAF if the State elected to use 2027 QHP premiums to determine the payment; if the State elected to use the 2026 QHP premiums, then we would use the modified PAF calculation described in this section. CMS would make a determination of whether or not a BHP was fully implemented based on a review of the Blueprint and provide that determination to the State.

We considered other approaches to the modified PAF. We considered whether or not CMS would collect data on the underlying CSR adjustment in the SLCSP premiums; however, we believe that such activities fall within States roles as BHP administrators and States are better able to work with QHP issuers to administer this data collection process. We also considered if States should survey all QHP issuers (not just those with the SLSCP premium). We believe that only using the CSR adjustment from individual market Exchange plans with the SLCSPs would be a more reasonable approach and would minimize the burden on States and QHP issuers by only requiring the State to work with one issuer in each region, as opposed to all issuers in each region. We also considered whether or not we should make further changes to the PAF, but we believe that this approach balances maintaining accurate BHP payments with stability and limited burden for BHP States. We request comments on this approach or alternative approaches to calculating the PAF.

2. Technical Clarification for Calculation of BHP Payment Rates in Cases of Multiple Second Lowest Cost Silver Plan Premiums in an Area

The BHP payment rates are based on the second lowest cost silver plan premium among individual market QHPs operating on the Exchanges in each rating area (or county) in a State. This is the basis for the reference premium (or RP) in the BHP payment methodology.

In general, we expect that each county would have a unique second lowest cost silver plan premium, which is used to calculate the payment rates for residents of that county for the BHP payment. However, in some cases, we have found that States may have more than one second lowest cost silver plan within a county. This may occur in cases where the State has allowed QHPs to operate in only a portion of the county instead of the entire county on the Exchange.

In our previous BHP payment methodologies, we do not describe how such a case would be handled for calculating BHP payments. In our technical guidance to States, we have instructed States to report the premiums for the second lowest cost silver plan operating in the largest part of the county as measured by total population.

Under the Secretary's general authority to account for all relevant factors necessary to determine the value of the premium and cost-sharing reductions that would have been provided to eligible individuals now enrolled in BHP coverage,[21] for the 2026 payment methodology and all subsequent years, we propose to clarify that in cases where there are more than one second lowest cost silver plans in a county, the BHP payment would be based on the premium of the second lowest cost silver plan applicable to the largest portion of the county as measured by total population. We welcome comments on this approach.

B. 45 CFR 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 ACA that transfers funds from issuers of lower-than-average risk, risk adjustment covered plans to issuers of higher-than-average risk, risk adjustment covered plans in the individual, small group markets, or merged markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program or have HHS do so on its behalf.[22] HHS did not receive any requests from States to operate risk adjustment for the 2026 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2026 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2025, the HHS-operated risk adjustment program is subject to the fiscal year 2025 sequestration.[23] The Federal government's 2025 fiscal year will begin on October 1, 2024. Therefore, the HHS-operated risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from fiscal year 2025 resources (that is, funds collected during the 2025 fiscal year).

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA),[24] as amended, and the underlying authority for the HHS-operated risk adjustment program, the funds that are sequestered in fiscal year 2025 from the HHS-operated risk adjustment program will become available for payment to issuers in fiscal year 2026 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

Additionally, we note that the Infrastructure Investment and Jobs Act[25] amended section 251A(6) of the BBEDCA and extended sequestration for the HHS-operated risk adjustment

[21] Section 1331(d)(3)(A)(ii) of the PHS Act.

[22] See also 42 U.S.C. 18041(c)(1).

[23] OMB. (2024). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2025. *https://www.whitehouse.gov/wp-content/uploads/2024/03/BBEDCA_251A_Sequestration_Report_FY2025.pdf.*

[24] Public Law 99–177 (1985).

[25] Public Law 117–58, 135 Stat. 429 (2021).

program through fiscal year 2031 at a rate of 5.7 percent per fiscal year.[26]

2. 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 State payment transfer formula[27] that is part of the HHS Federally certified 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,[28] and prescription drug categories (RXCs) beginning with the 2018 benefit year.[29] Starting with the 2023 benefit year, we removed the severity illness factors in the adult models and added interacted HCC count factors (that is, additional factors that express the presence of a severity or transplant HCC in combination with a specified number of total payment HCCs or HCC groups on the enrollee's record) to the adult and child models[30] applicable to certain severity and transplant HCCs.[31]

Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a cost sharing reduction (CSR) adjustment factor. 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 (PLRS)) within a geographic rating area is one of the inputs into the 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 for a given benefit year. 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. Data for HHS Risk Adjustment Model Recalibration for the 2026 Benefit Year

We are proposing to recalibrate the 2026 benefit year HHS risk adjustment models with the 2020, 2021, and 2022 enrollee-level EDGE data. Consistent with the approach outlined in the 2020 Payment Notice, we propose to recalibrate the HHS risk adjustment models for the 2026 benefit year using only enrollee-level EDGE data, and to continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2026 benefit year model recalibration.[32] Additionally, as outlined in the 2022 Payment Notice (86 FR 24140, 24152), we propose to use the 3 most recent consecutive years of enrollee-level EDGE data that are available at the time we estimate the draft recalibrated coefficients published in the proposed rule for the applicable benefit year.[33] We believe this promotes stability, meets the goal of the HHS-operated risk adjustment program, and allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year.

In the 2024 Payment Notice (88 FR 25740 through 25749), we finalized the use of 2018, 2019 and 2020 benefit year enrollee-level EDGE data for recalibration of the 2024 benefit year HHS risk adjustment models for all model coefficients. As explained in the 2024 Payment Notice proposed rule (87 FR 78215 through 78216) and final rule (88 FR 25749 through 25753), we analyzed the 2020 benefit year data to identify possible impacts of the COVID–19 Public Health Emergency (PHE). Our analysis generally found that the 2020 enrollee-level EDGE data were anomalous primarily in the volume and frequencies of certain types of claims, but that the relative costs of specific services, at least those associated with payment HCCs in the HHS risk adjustment models, were largely unaffected. Because the HHS risk adjustment models predict relative costs of care for specific conditions on an enrollee-level basis and tend not to rely on overall patterns of utilization, the minimal impacts to relative costs of care for payment HCCs likewise resulted in minimal impacts on the coefficients fitted by the 2020 enrollee-level EDGE recalibration data.

Then, in the 2025 Payment Notice (89 FR 26236 through 26238), we finalized the use of 2019, 2020 and 2021 benefit year enrollee-level EDGE data for recalibration of the 2025 benefit year HHS risk adjustment models for all model coefficients. As explained in the 2025 Payment Notice proposed rule (88 FR 82527 through 82529) and final rule (89 FR 26236 through 26238), we recognized that the COVID–19 PHE was still in effect throughout the 2021 benefit year.[34] Therefore, similar to our analysis of 2020 benefit year data to identify possible impacts of the COVID–19 PHE, we conducted additional analyses to determine whether any anomalies in the 2021 benefit year enrollee-level EDGE data were present beyond expected year-to-year variation and whether the use of 2 years of PHE-impacted data presented any additional concerns. Our analysis found that the coefficients for the 2021 benefit year enrollee-level EDGE recalibration data were similar to the 2019 and 2020 benefit year's coefficients, with levels of variation consistent with typical changes in coefficients for new years of data. We did not identify any significant anomalies and incorporated the 2021 benefit year enrollee-level EDGE data in the 2025 risk adjustment model recalibration without exception.

Consistent with the approach for use of 2020 and 2021 benefit year enrollee-level EDGE data, we performed reviews of the 2022 benefit year enrollee-level EDGE data to identify potential anomalies prior to incorporating the 2022 benefit year enrollee-level EDGE data as part of the proposed recalibration of the HHS risk adjustment models for the 2026 benefit year. Our review did not identify systematic anomalies in the 2022 enrollee-level EDGE data. Therefore, after considering our analysis of the 2020, 2021 and 2022

[26] 2 U.S.C. 901a.

[27] The State payment transfer formula refers to part of the Federally certified risk adjustment methodology that applies in States where HHS is responsible for operating the program. The formula 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). See, for example, 81 FR 94080.

[28] For the 2017 through 2022 benefit years, there is a set of 11 binary enrollment duration factors in the adult models that decrease monotonically from 1 to 11 months, reflecting the increased annualized costs associated with fewer months of enrollments. See, for example, 81 FR 94071 through 94074. These enrollment duration factors were replaced beginning with the 2023 benefit year with HCC-contingent enrollment duration factors for up to 6 months in the adult models. See, for example, 87 FR 27228 through 27230.

[29] 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 models. See, for example, 83 FR 16941.

[30] See table 4 for a list of factors in the adult models, and table 5 for a list of factors in the child models.

[31] See 87 FR 27224 through 27228. Also see table 6 below.

[32] 84 FR 17463 through 17466.

[33] Although we do receive the next year of enrollee-level EDGE data prior to the proposed rule, that data must go through several quality and analysis checks before it is useable for HHS risk adjustment model recalibration.

[34] See, for example, ASPR. (2023, February 9). Renewal of Determination that a Public Health Emergency Exists. *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx.*

enrollee-level EDGE data, we propose to determine coefficients for the 2026 benefit year HHS risk adjustment models based on a blend of separately solved coefficients from the 2020, 2021, and 2022 benefit years' enrollee-level EDGE data, with the costs of services identified from the data trended between the relevant year of data and the 2026 benefit year.[35] The draft coefficients listed reflect the use of trended 2020, 2021, and 2022 benefit year enrollee-level EDGE data, as well as other HHS risk adjustment model updates proposed in this proposed rule (including, for example, the proposed phasing out of the pricing adjustment for Hepatitis C drugs).[36] However, we note that the draft coefficients could change between the proposed and final rule if we identify an error after publication of this proposed rule or if any proposed models are modified or not finalized 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 publication in the final rule, we would publish the final coefficients for the 2026 benefit year in guidance soon after the publication of the final rule.

We seek comment on the proposal to determine 2026 benefit year coefficients for the HHS risk adjustment models based on a blend of separately solved coefficients from the 2020, 2021, and 2022 enrollee-level EDGE data.

[35] As described in the *2016 Risk Adjustment White Paper* (*https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf*) and the 2017 Payment Notice (81 FR 12218), we subdivide expenditures into traditional drugs, specialty drugs, medical services, and preventive services and determine trend factors separately for each category of expenditure. In determining these trend factors, we consult our actuarial experts, review relevant Unified Rate Review Template (URRT) submission data, analyze multiple years of enrollee-level EDGE data, and consult National Health Expenditure Accounts (NHEA) data as well as external reports and documents published by third parties. In this process, we aim to determine trends that reflect changes in cost of care rather than gross growth in expenditures. As such, we believe the trend factors we used for each expenditure category for the proposed 2026 benefit year models are appropriate for the most recent changes in cost of care that we have seen.

[36] Additionally, this rulemaking includes a proposal to incorporate pre-exposure prophylaxis (PrEP) into a separate model factor in the HHS risk adjustment adult and child models for the 2026 benefit year. Although a separate proposed PrEP risk adjustment model factor is not included in tables 4 through 9, we do provide a comprehensive analysis of our considerations and structure for including a separate PrEP risk adjustment model factor, including the impact of the proposed addition of a PrEP factor on other model factors in that section of this rulemaking.

b. Pricing Adjustment for the Hepatitis C Drugs

Beginning with the 2026 benefit year, we propose to begin phasing out the market pricing adjustment [37] to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models and start trending Hepatitis C drugs consistent with the other drugs [38] in the HHS risk adjustment models. Since the 2020 benefit year HHS risk adjustment models, we have included a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the models.[39] The purpose of this market pricing adjustment was to account for significant pricing changes between the data years used for recalibrating the models and the applicable benefit year of risk adjustment as a result of the introduction of new and generic Hepatitis C drugs.[40] We have committed to annually reassessing the Hepatitis C pricing adjustment with additional years of enrollee-level EDGE data as the data becomes available.

As part of the 2026 benefit year model recalibration analysis, we reassessed the cost trend for Hepatitis C drugs using available enrollee-level EDGE data (including 2022 benefit year data) to consider whether the pricing adjustment was still needed and, if it is still needed, whether it should be modified. We found that projected costs for Hepatitis C drugs have begun to rise alongside the expected cost of other specialty drugs after many years of decline and stagnation due to the introduction of new and generic Hepatitis C drugs. Therefore, we believe that it is appropriate to begin phasing out the market pricing adjustment for Hepatitis C drugs and start trending the cost of these drugs consistent with other similar drugs in the HHS risk adjustment models to ensure that we continue to use the most appropriate estimates of the average cost of Hepatitis C treatments for recalibration of the HHS risk adjustment models for the 2026 benefit year and beyond.

To explain further, because the annual recalibration of our risk adjustment models use the most recent 3 years of enrollee-level EDGE data available at the time of the proposed rule (in the case of this proposed rule and the recalibration of the 2026 benefit year models: the 2020, 2021, and 2022 enrollee-level EDGE data) in our simulation of plan liability for the applicable benefit year, we apply trend factors to different categories of medical expenditures, including specialty drugs, for every calendar year between the applicable benefit year and each year of enrollee-level EDGE data.[41] [42] For example, to project costs for 2026 benefit year risk adjustment, we trend the 2020 enrollee-level EDGE data forward 6 years, the 2021 enrollee-level EDGE data forward 5 years, and the 2022 enrollee-level EDGE forward four years. We have previously developed the Hepatitis C market pricing adjustment by applying a separate annual trend factor to Hepatitis C drugs in lieu of applying the annual specialty drug trend we apply to all other specialty drugs. The intent of this adjustment is to track the projected decrease and stagnation of Hepatitis C drug prices due to the introduction of new and generic versions of Hepatitis C drugs as identified in various sources of available market data [43] and through consultation with our actuarial experts. As illustrated by table 1, this proposal would continue to trend Hepatitis C drugs separately from specialty drugs to project decrease and stagnation of Hepatitis C treatment pricing changes

[37] For discussion relating to the Hepatitis C Pricing Adjustment for previous benefit years, *see,* for example, 89 FR 26237 through 26238.

[38] See 81 FR 12218 through 12219.

[39] 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.

[40] See Milligan, J. (2018). A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV. Gilead. *https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.* See also AbbVie. (2017). AbbVie Receives U.S. FDA Approval of MAVYRETTM (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1–6) in as Short as 8 Weeks. Abbvie. *https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.* See also Silseth, S., & Shaw, H. (2021). Analysis of prescription drugs for the treatment of hepatitis C in the United States [White paper]. Milliman. *https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx.*

[41] See, supra, notes 38 and 39.

[42] Because EDGE data do not generally account for drug rebates per the EDGE Business Rules (available at *https://regtap.cms.gov/reg_librarye.php?i=3765*), for the purposes of risk adjustment recalibration, we also incorporate assumptions about the incidence of drug rebates in our trending of prescription drug data.

[43] See 88 FR 25753–25754. See also, Silseth, S., & Shaw, H. (2021). *Analysis of prescription drugs for the treatment of Hepatitis C in the United States. Milliman White Paper. https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx.* See also, Cline, M., Schweitzer, K., Sileth, S., & Wang, M. (2021). *Projected U.S. national hepatitis C treatment costs and estimated reduction to medical costs. Milliman White Paper. https://www.milliman.com/-/media/milliman/pdfs/2021-articles/9-22-21-hcv-treatment-and-medical-cost-whitepaper.ashx.* See also, supra, note 35.

between 2020 and 2021 (for the 2020 EDGE data), between 2021 and 2022 (for the 2020 and 2021 EDGE data), and between 2022 and 2023, between 2023 and 2024, and between 2024 and 2025 for all three data years (2020, 2021, and 2022 EDGE data) used for recalibration of the 2026 benefit year HHS risk adjustment models. Once we have trended Hepatitis C costs to reflect no growth from the 2020, 2021, and 2022 enrollee-level EDGE data to the 2025 benefit year, under this proposal for 2026 benefit year risk adjustment, we would complete the trending of these 3 years of data from the 2025 benefit year to the 2026 benefit year by applying the specialty drug trend factor, rather than the Hepatitis C trend factor that reflects the unique market pricing adjustment for these drugs.

In other words, we propose to adopt a phased approach (See table 1) to transition the Hepatitis C drugs' trending as part of the annual recalibration of the HHS risk adjustment models beginning with the 2026 benefit year to move away from the current unique market pricing adjustment for these drugs and align with the trending approach for specialty drugs as we expect that the current growth in Hepatitis C drug costs will continue to be similar to growth in specialty drug costs in future years. As described above, to begin this transition for the 2026 benefit year HHS risk adjustment models, we propose to apply the specialty drug trend to 1 year of trending Hepatitis C treatment costs (that is, the trend from 2025 to 2026) for all 3 years of enrollee-level EDGE data used in recalibration (that is, 2020, 2021, and 2022 enrollee-level EDGE data). These 3 years of enrollee-level EDGE data would otherwise be trended forward using the lower trend rate reflecting the market pricing adjustment for Hepatitis C treatments through the 2025 benefit year. As such, 2026 benefit year recalibration data for Hepatitis C would reflect 1 year of growth in the cost of treatment at the same rate as other specialty drugs. To continue the transition of phasing out the Hepatitis C drug pricing adjustment in future benefit years' annual model recalibration, under this proposal, we would annually increase the number of years for which we would use the specialty drug trend and decrease the number of years that would use the unique market pricing adjustment for Hepatitis C drugs. For example, as seen in table 1, for the recalibration of the 2027 benefit year HHS risk adjustment models, under this proposal, we would apply the specialty drug trend to 2 years of the trending used in the models to project growth in Hepatitis C drugs. Specifically, assuming that the 2027 benefit year would use 2021, 2022, and 2023 enrollee-level EDGE data for the annual model recalibration, we would project Hepatitis C treatment pricing changes reflecting the unique market pricing adjustment between 2021 and 2022 (for the 2021 EDGE data), between 2022 and 2023 (for the 2021 and 2022 EDGE data), and between 2023 and 2024 and between 2024 and 2025 for all three data years (2021, 2022, and 2023 EDGE data) used for the recalibration of the 2027 benefit year HHS risk adjustment models. Again, once we have trended Hepatitis C drug costs to reflect the unique market pricing adjustment from the 2021, 2022, and 2023 enrollee-level EDGE data to the 2025 benefit year, under the proposed transitional approach, for recalibration of the 2027 benefit year HHS risk adjustment models, we would complete the trending of these 3 years of data from the 2025 benefit year to the 2027 benefit year by applying the specialty drug trend factor between the 2025 and 2026 benefit years and between the 2026 and 2027 benefit years. This approach would continue until such time as all enrollee-level EDGE data years used for the recalibration of the HHS risk adjustment models are from benefit year 2025 or later (See table 1), at which time the specialty drug cost trend would be fully applied to Hepatitis C drug costs consistent with other specialty drugs in the HHS risk adjustment models and we would stop applying the separate market pricing adjustment for Hepatitis C drugs as part of the annual model recalibration.

TABLE 1: Proposed Transition of the Hepatitis C Market Pricing Adjustment (Hep C Trend) to the Specialty Drug Trend for HHS Risk Adjustment Model Recalibration

Year of EDGE Data	Year-to-Year Trend Rate Used								
	2020-2021	2021-2022	2022-2023	2023-2024	2024-2025	2025-2026	2026-2027	2027-2028	2028-2029
2020 Data Year	Hep C Trend	Hep C Trend	Hep C Trend	Hep C Trend	Hep C Trend	Specialty Drug Trend	--*	--*	--*
2021 Data Year	--	Hep C Trend	Hep C Trend	Hep C Trend	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	--*	--*
2022 Data Year	--	--	Hep C Trend	Hep C Trend	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	--*
2023 Data Year	--	--	--	Hep C Trend	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend
2024 Data Year	--	--	--	--	Hep C Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend
2025 Data Year	--	--	--	--	--	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend	Specialty Drug Trend

*Data year projected to no longer be used for the applicable benefit year recalibration

We propose this transitional approach because we continue to believe a market pricing adjustment specific to Hepatitis C drugs in the simulation of plan liability as part of the annual recalibration of the HHS risk adjustment models for benefit years that involve the use of enrollee-level EDGE data prior to 2025 (for example, for 2026 recalibration, the 2020 through 2022 enrollee-level EDGE data, and the 2023 through 2025 intermediate years of trending) is necessary and appropriate to account for the lack of growth in Hepatitis C drug prices relative to other prescription drugs in the market between those data years and the 2025 benefit year.

We seek comment on our proposal to phase out the market pricing adjustment and trend Hepatitis C drugs consistent with other specialty drugs starting with the annual recalibration of the 2026 benefit year HHS risk adjustment models.

c. Proposed Inclusion of Pre-Exposure Prophylaxis (PrEP) in the HHS Risk Adjustment Adult and Child Models as an Affiliated Cost Factor (ACF)

We are proposing to incorporate human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) as a separate, new type of factor called an Affiliated Cost Factor (ACF) in the HHS risk adjustment adult and child models starting with the 2026 benefit year. This proposed change would reflect an evolution in our approach to defining the factors used in the HHS risk adjustment models to include a factor that is not indicative of an active condition and would change our current policy that models the costs of PrEP alongside all other preventive services.

Starting with the 2021 benefit year HHS risk adjustment models, as finalized in the 2021 Payment Notice (85 FR 29185 through 29187), we incorporated PrEP in the simulation of plan liability in the HHS risk adjustment adult and child models as a preventive service with zero cost sharing after careful analysis of preventive drugs that are recommended at grade A or B by the United States Preventive Services Task Force (USPSTF), including analysis on when PrEP can used as a preventive service.[44] Specifically, in June 2019, the USPSTF recommended the use of PrEP as a preventive service for persons who are at high risk of HIV acquisition.[45] Because Section 2713 of the PHS Act, as added by Section 1001 of the ACA, requires that non-grandfathered group health plans and health insurance issuers in the group and individual markets cover certain recommended preventive services without imposing cost sharing,[46] we modified the

[44] See 85 FR 29185 through 29187.

[45] See US Preventive Services Task Force. *Preexposure* prophylaxis for the prevention of HIV infection: US Preventive Services Task Force recommendation statement. *JAMA*. 2019;321(22):2203–2213. The USPSTF issued an updated recommendation on August 22, 2023. The updated recommendation is available at *https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis*.

[46] On March 30, 2023, the United States District Court for the Northern District of Texas issued a final judgment in the case *Braidwood Management Inc.* v. *Becerra,* Civil Action No. 4:20–cv–00283–O (N.D. Tex. Mar. 30, 2023) holding that that the USPSTF's recommendations operating in conjunction with PHS Act section 2713(a)(1) violate the Appointments Clause of Article II of the United States Constitution and are therefore unlawful. On appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court on the merits but held that prospective and retrospective relief was limited to the named plaintiffs. The case was remanded to the District Court for further proceedings. On August 28, 2024, based on the Defendants' intent to file a petition for writ of certiorari by September 19, 2024, the District Court

Continued

simulation of plan liability as part of the annual recalibration of the HHS risk adjustment adult and child models to account for the higher level of cost sharing associated with its status as a preventive service, similar to how we treat other preventive services.

As a general principle, we currently incorporate preventive services into each of the HHS risk adjustment models to ensure that 100 percent of the cost of those services are reflected in the simulation of plan liability. In the simulation of plan liability, services are only counted as preventive when they occur in the recommended circumstances (for example, age) to the extent we can identify such circumstances from enrollee-level EDGE data. As with other preventive services, the incorporation of PrEP into the simulation of plan liability as a preventive service tends to impact the age-sex coefficients for the population that is most likely to utilize the given preventive service. For PrEP, this population is typically males between the ages of 25 and 39, because this group composes the most frequent utilizers of PrEP in the enrollee-level EDGE data. In addition to PrEP drugs, like other preventive services,[47] ancillary services related to PrEP care (for example, HIV screenings) qualify as preventive services and as such are also currently calibrated at 100 percent plan liability in the recalibration of the HHS risk adjustment adult and child models.[48]

However, as a part of our commitment to consider ways to continually improve the HHS risk adjustment models, we continued to monitor and assess different ways to incorporate PrEP in the HHS risk adjustment models. In this regard, since the adoption of the current approach beginning with the 2021 benefit year HHS risk adjustment adult and child models, we have continued to assess the incorporation of PrEP into these models as we do other preventive services. We have also continued to receive recommendations from some interested parties that PrEP be incorporated into the HHS risk adjustment adult models differently than other preventive services in the calculation of plan liability due to the high cost of PrEP. We previously considered changing the treatment of PrEP to incorporate it in the HHS risk adjustment adult models as an RXC; however, we have always been concerned with this approach because RXCs are specifically incorporated as separate factors to impute a missing diagnosis or indicate severity of a diagnosis.[49] As such, we did not incorporate PrEP into RXC 1 (Anti-HIV Agents) because PrEP utilization does not indicate an HIV/AIDS diagnosis or the severity of a diagnosis. We also considered incorporating the use of PrEP in the HHS risk adjustment models as a separate HCC, but we did not believe that approach would be appropriate because the principles for including an HCC into the models require that each HCC represents well-specified, clinically significant, chronic or systematic medical conditions.[50] Because there is no active chronic medical condition involved, the use of PrEP for prevention of an HIV infection does not satisfy these criteria either.

Additionally, when we initially incorporated PrEP as a preventive service in the simulation of plan liability in the HHS risk adjustment adult and child models, we expected that any risk of adverse selection regarding PrEP would decrease over time as we expected the costs of PrEP to decrease due to generics entering the market and gaining market share. We also expected minimal differences in issuers' populations of PrEP users because, under Section 2713 of the PHS Act and its implementing regulations at 45 CFR 147.130, all issuers of risk adjustment covered plans are required to cover PrEP and its ancillary services at zero cost sharing, consistent with the applicable USPSTF recommendation. Thus, we anticipated that the expected similarity across issuers' PrEP-associated cost sharing parameters would also mitigate the risk of adverse selection.

More recently, we have continued to analyze PrEP and its usage in the individual, small group, and merged markets as additional benefit years of enrollee-level EDGE data became available. Because of PrEP's high costs relative to other preventive services, and in contrast to our initial assumptions about pricing decreases, our analysis of 2022 benefit year enrollee-level data[51] found that PrEP services can pose a unique risk of adverse selection to the extent that utilization of PrEP services differs between plans. More specifically, our analysis found that there are statistically significant, substantial differences in PrEP prevalence between issuers in rating areas where PrEP use is most common, indicating that the addition of a PrEP factor in the adult and child risk adjustment models would be appropriate and would have a meaningful impact on risk adjustment State transfers. Furthermore, our analysis also found that other considerations that helped inform the current approach (such as the expected decrease in costs as generics entered the market and gained market share) have not addressed the uniquely high costs of PrEP as a preventive service as we previously expected. For these reasons, we started to reconsider our approach and whether it should evolve to address other costs in the market (such as PrEP) that could impact the assessment of actuarial risk but which do not indicate the presence of a specific diagnosis.

We therefore tested incorporating a non-RXC and non-HCC model factor for PrEP in the HHS risk adjustment adult and child models to capture differences in costs for PrEP utilizers relative to the average enrollee. To signify that the potential new factor would not indicate the presence of a specific active medical condition, we refer to the potential new type of factor as an ''affiliated cost factor'' (ACF), thereby distinguishing this new type of potential factor from RXCs and HCCs.

Generally speaking, similar to our approach when determining the HCCs and RXCs to be included in the HHS risk adjustment models,[52] if adopted, we would rely on a set of principles to guide our decision making in developing any new ACF variable.

Principle 1—Like HCCs and RXCs, an ACF should be clinically meaningful, but in the case of ACFs, such variables

issued an order to stay proceedings in the District Court through the conclusion of proceedings in the United States Supreme Court. The Departments filed a petition for writ of certiorari on September 19, 2024. *Braidwood Mgmt., Inc.* v. *Becerra,* Civil Action No. 23–10326 (5th Cir. June 21, 2024), *petition for cert filed,* U.S. Sept. 19, 2024 (24–316).

[47] For example, colonoscopies typically require a combination of several services between the drugs needed for the colonoscopy and the professional and institutional claims for the visit and procedure itself. Likewise, contraception coverage often requires a doctor's visit to obtain a prescription for the contraception.

[48] See 86 FR 24164.

[49] See the 2018 Payment Notice (81 FR 94074 through 94080). See also the March 31, 2016, *HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers.* June 8, 2016. Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf.*

[50] See CMS. (2021). *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* Section 1.2.1 (Principles of Risk Adjustment). *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[51] Prior to the 2021 Benefit Year, Plan ID and Rating Area were not included as part of the enrollee-level data extracted from issuers' EDGE data submissions. As finalized in the 2023 Payment Notice (87 FR 27241 through 27251), we now extract these fields as part of the enrollee-level EDGE dataset and are able to include them in our analyses. As such, this analysis and proposal reflects our earliest opportunity to reliably detect differences in prevalence within rating areas for any medical expenditures, including PrEP.

[52] See the 2014 Payment Notice Proposed Rule (77 FR 73128). See, also, the 2018 Payment Notice Proposed Rule (81 FR 61470).

would be comprised of National Drug Codes (NDCs) or procedure codes that are not indicative of a diagnosis for a specific serious medical condition, in contrast to HCCs and RXCs. In other words, an ACF may refer to a preventive service (as in the case of a potential PrEP ACF), or to classes of treatments that may be applicable to a wide variety of disease states and are therefore too general to indicate a specific diagnosis. Nevertheless, codes included in an ACF should all relate to a reasonably well-specified pharmacologic, therapeutic or chemical characteristic that defines the category. The adherence to the principle of clinical meaningfulness maintains the face validity of the classification system and the models' interpretability.

Principle 2—Like HCCs and RXCs, ACFs should meaningfully predict total medical and drug expenditures. Additionally, NDCs and procedure codes in an ACF should be reasonably homogeneous for their effect on current year costs, that is, the annual costs associated with NDCs or procedure codes triggering the ACF should fall within a reasonably limited range. Relative to the majority of NDCs or procedure codes in a given ACF, there should not be any extremely low or high cost NDCs or procedure codes included in the ACF.

Principle 3—Like HCCs and RXCs, because ACFs would affect State transfers, these factors should have adequate sample sizes to permit accurate and stable estimates of expenditures. For example, it is difficult to reliably determine the expected cost of extremely rare categories.[53]

Principle 4—Like HCCs and RXCs, in creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each disease process, where appropriate, while the effects of unrelated disease processes accumulate. Therefore, related HCCs, RXCs and ACFs should be treated hierarchically such that the most severe manifestation of a given specific potential disease process principally defines its impact on costs. As such, the presence of a relevant HCC or RXC in an enrollee's medical record, which would indicate the presence of a specific active medical condition, should preclude the application of a related ACF because ACFs do not indicate the presence of a specific active medical condition.

Principle 5—As with HCCs and RXCs, issuers should not be penalized for a provider prescribing additional NDCs or coding additional medical conditions (monotonicity). This principle has two consequences for modeling of ACFs: (1) Like HCCs and RXCs, ACFs should not carry a negative payment weight; and (2) an HCC or RXC, or a relevant combination of an HCC, RXC, and interaction factor(s), reflecting the presence of a potential disease process to which the ACF is directly related should have at least as large a payment weight as the ACF.

Principle 6—Like RXCs, we expect ACFs to primarily be composed of NDCs or service codes. As such, the classification for ACFs, like RXCs, should assign NDCs or service codes to only one ACF or RXC variable (mutually exclusive classification). Because each NDC can map to more than one RXC or ACF, the classification should map NDCs to the primary RXC or ACF variable based on considerations such as route of administration, intended application of the product, ingredient list identifier, label, dosage form, and strength of the drug.

Principle 7—As with HCCs and RXCs, in evaluating the inclusion of ACFs, discretionary and noncredible drug or diagnosis categories should be excluded from payment models. ACFs that are particularly subject to prescribing variation or inappropriate prescribing by health plans or providers or to intentional or unintentional discretionary coding, or that are not clinically or empirically credible as cost predictors, should not be included.

In developing an ACF variable reflecting PrEP, we are considering whether PrEP satisfies these principles and what approaches are necessary to appropriately balance all seven principles. A PrEP ACF would easily satisfy Principle 1 (clinically meaningful and specific), Principle 2 (meaningful and predictable costs [54]), Principle 3 (sample size), and Principle 7 (low risk of inappropriate prescribing). PrEP is a well-defined regimen of medication that is only recommended to enrollees who meet certain risk factors,[55] providing clinical meaningfulness and specificity. Regarding cost, with the exception of generics,[56] the commonly available forms of PrEP are expensive and have similar costs,[57] making the costs both meaningful and predictable. Furthermore, there are a sufficient number of enrollees in the enrollee-level EDGE data to produce a reliable estimate of PrEP costs for the HHS risk adjustment adult and child models. Finally, for a preventive service such as PrEP, we consider the uniquely high costs and low likelihood of over-prescribing to provide clinical and empirical credibility towards cost prediction, thereby satisfying the low risk of inappropriate prescribing required by Principle 7. Specifically, we consider there to be a low likelihood of overprescribing PrEP due to the high degree of ancillary services generally required to obtain and maintain access to a PrEP prescription. For example, as reflected by the U.S. Public Health Service clinical practice guidelines for PrEP,[58] patients receiving oral PrEP generally must see a provider to be tested for HIV and other sexually transmitted infections every 3 months and have key liver and kidney function indicators tested every 6 months to 1 year.[59] Additionally, we suspect [60] that

[53] For example, one extremely rare category that we have continued to analyze and consider for incorporation in the HHS risk adjustment models is gene therapy treatments. However, because these treatments are for rare conditions, and because there is substantial variation in costs from patient to patient for these treatments, through our ongoing monitoring and consideration of gene therapy treatments, we continue to find insufficient sample size and stable estimates of costs for the purposes of creating a new factor for these treatments in the HHS risk adjustment models.

[54] As discussed later in this section, it may be appropriate to remove generic drugs to ensure homogeneity of costs within a PrEP ACF.

[55] See Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. *https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf)*

[56] See, supra, note 54.

[57] See NADAC (National Average Drug Acquisition Cost) 2024 reference data (available at *https://data.medicaid.gov/dataset/99315a95-37ac-4eee-946a-3c523b4c481e*) and the NADAC Equivalency Metrics (available at *https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf*). See also *https://getprepbroward.com/documents/Long-Acting-Injectable-PrEP.pdf* for estimates of the cost of Long Acting Injectable PrEP, which is administered by a provider in a clinical setting and is not available in NADAC data.

[58] See, supra, note 55.

[59] The costs of these ancillary services are currently captured in the age-sex coefficients, but the addition of a PrEP ACF to the HHS risk adjustment adult and child models would shift the risk contributed by ancillary services out of the age-sex factors into the PrEP ACF factor.

[60] In the enrollee-level EDGE data, we are unable to assess utilization rates from PrEP indicated populations because we are generally unable to identify the population of enrollees who would be eligible for PrEP but who are not utilizing the preventive service. Additionally, specific estimates of PrEP utilization among specific indicated populations are difficult to attain from other data sources at this point in time. The CDC has paused the publication of estimates of PrEP coverage in indicated populations and has advised against citing specific data points until June 2025 due to data availability issues. (See Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 territories and freely associated States, 2022. *HIV Surveillance Supplemental Report* 2024; 29(No. 2). *https://www.cdc.gov/hiv-data/nhss/national-hiv-prevention-and-care-outcomes.html*).

there is a relatively low utilization rate of PrEP services among specific indicated populations, which would also indicate a low likelihood that PrEP is being overprescribed.

As mentioned above, we have found that PrEP overall satisfies Principle 2, having meaningful and predictable costs. In particular, our analyses found that the utilization patterns of PrEP medications have been fairly consistent year-over-year, with previously approved versions of PrEP medications maintaining substantial market share despite the availability of generic versions and new market entrants such as Apretude. If ACF medications and services that were commonly used in 1 year were largely supplanted by different medications or services in the following year, the cost predictions based on previous years of data may be inaccurate. Nevertheless, although we will continue to monitor the market for PrEP drugs, we generally do not anticipate substantial decrease in costs in the near future for enrollees taking brand name drugs due to the more convenient drugs and dose-forms (for example, long-acting injectable forms) coming to market [61] and the retention of market share by existing branded drugs.

Despite the overall anticipation that PrEP costs are consistent and will remain high over the next several years, we have found that there exists a large disparity in the costs of generic PrEP medication and the costs of brand name PrEP medication.[62] Due to this disparity, if we include all PrEP medications in the definition of an ACF, the estimated coefficient will likely lead to overprediction for enrollees receiving generic medications and underprediction for enrollees receiving brand name medications. As such, it may be appropriate to exclude generic PrEP medication from the PrEP ACF, if one is adopted, which would exclude about 50 percent of enrollees with a PrEP prescription claim from the calculation of a PrEP ACF coefficient according to 2022 enrollee-level EDGE data. Such a low-cost exclusion from the ACF may improve predictions for enrollees receiving either generic or brand name PrEP medication and has precedent in our adoption of other factors in the HHS risk adjustment models. Specifically, we previously excluded generic drugs from RXC 9, Immune Suppressants and Immunomodulators, due to concern over patient access and health plan selection behavior.[63] However, we believe that such an exclusion for a potential PrEP ACF could create incentives for prescribing brand over generic PrEP and therefore we solicit comments on balancing these considerations to help inform our consideration of the design of a potential PrEP ACF variable.

As outlined by our discussion of Principles 1, 2, 3, and 7, our preliminary testing found minimal empirical concerns with a new PrEP ACF variable being added to the current HHS risk adjustment adult and child models, as the sample size for such a variable is reasonable for both the adult and child models, the clinical specifications are well defined, costs are generally predictable, and the resulting preliminary coefficient estimates for PrEP in the adult and child models are meaningful. However, in assessing Principles 4 (hierarchical factor definitions), 5 (monotonicity), and 6 (mutually exclusive classification), we found that the creation of a PrEP ACF variable would require further careful consideration.

To satisfy Principle 4 (hierarchical factor definitions), the most severe manifestation of a given specific potential disease process must principally define its impact on costs. Therefore, related HCCs and RXCs (in the case of a PrEP ACF, the related HCC 1 for HIV/AIDS, and RXC 1 for anti-HIV agents) should be treated hierarchically. As such, in considering PrEP as a potential ACF, the presence of HCC 1 or RXC 1 in an enrollee's medical record should preclude the application of the PrEP ACF, as the prevention of HIV infection clearly indicates a less severe manifestation of the specific potential disease process than treatment of an active HIV infection.

However, the coefficient for HIV/AIDS (HCC 1) in the adult models [64] has generally been lower than the coefficient we estimate would be calculated for a PrEP ACF. As such, without constraints applied to the HCC 1, RXC 1, and PrEP ACF coefficients, an adult enrollee who was on PrEP and later tested positive for HIV but did not start anti-retroviral therapy for treatment within the same benefit year would have their risk score decrease between the initial application of the PrEP ACF, and its later replacement with HCC 1, violating monotonicity (Principle 5). Such enrollees make up a very small proportion of enrollees with a PrEP prescription claim (approximately 1.9 percent of enrollees with a PrEP prescription claim in the 2021 enrollee-level EDGE data). Additionally, this violation of monotonicity is not expected to take place in the HHS risk adjustment child models, as the lack of RXCs in the child models causes the coefficient for HCC 1 to be high enough that a PrEP ACF coefficient would not exceed the HCC for HIV/AIDS among child enrollees. Nevertheless, for consistency with the established principles for the HHS-operated risk adjustment program and the proposed principles to guide development of potential new ACF variables, we are considering solutions, described below, to the monotonicity concern for a PrEP ACF in the HHS risk adjustment adult models should we finalize the adoption of the proposed factor.

Additionally, a PrEP ACF could pose issues for mutually exclusive classification (Principle 6). Specifically, the compounds used in PrEP medication are also used to treat HIV. As such, NDCs for medications used for PrEP or the individual compounds alone are not enough to distinguish between an enrollee receiving PrEP and an enrollee in treatment for an active HIV infection. However, due to the necessity of the additional anti-retroviral compounds for HIV infection treatment, with special considerations and data filtering, we are generally able to distinguish enrollees that are receiving antiretroviral therapy for PrEP and those receiving antiretroviral treatment as treatment for HIV/AIDS for the purposes of calculating plan liability with 100 percent cost sharing for PrEP and typical cost sharing treatment of HIV infection.[65] [66] To address the

[61] Long-acting injectable PrEP may be beneficial in encouraging adherence to a PrEP medication regimen. (See, for example, *https://getprepbroward.com/documents/Long-Acting-Injectable-PrEP.pdf*). As such, we anticipate that treatment guidelines may recommend its use over oral PrEP in the future.

[62] See, supra, note 57.

[63] See, for example, the 2019 Payment Notice (83 FR 16942).

[64] Risk associated with HIV infection can be expressed in the value of HCC 1 or in the value of RXC 1. Because these factors are highly correlated, the value of each coefficient taken alone may fluctuate between benefit years. However, the additive value of these two factors in the HHS risk adjustment adult models is fairly consistent year-over-year.

[65] See the 2021 Payment Notice (85 FR 29187).

[66] The medications used to treat HIV are also used as post-exposure prophylaxis (PEP). Unlike PrEP, we are unable to distinguish between prescriptions for HIV treatment and prescriptions for PEP because the current guidelines for known exposures to HIV recommend the prescription of the same drugs as are used in treatment (See for example, *https://stacks.cdc.gov/view/cdc/20711*) *https://stacks.cdc.gov/view/cdc/20711*). However, we note that PEP requires a 28-day treatment regimen and, as such, has a much more limited impact on calculations of plan liability and risk than either treatment for an active HIV infection or PrEP. (See, for example, *https://hivinfo.nih.gov/understanding-hiv/fact-sheets/post-exposure-prophylaxis-pep#:~:text=PEP%20stands%20for%20post%2Dexposure,used%20only%20in%20emergency%20situations.*)

concerns for adherence to Principle 6, we will need to create a mutually exclusive NDC classification between RXC 1 and a PrEP ACF.

To address the HHS risk adjustment adult modeling concerns we identified regarding Principles 4, 5 and 6, we are considering two alternative approaches. First, we could modify the current definition of RXC 1 (Anti-HIV agents) by treating PrEP NDCs as RXC 1 NDCs in limited circumstances based on individual enrollee characteristics. Alternatively, we could place the PrEP ACF in a hierarchy with RXC 1 but define no hierarchical restrictions between PrEP and HCC 1 (HIV/AIDS). We discuss these alternatives in detail below.

Under the first approach, modifying the current definition of RXC 1, we would add PrEP NDCs into RXC 1 (Anti-HIV agents) in limited circumstances to address situations where the adult enrollee has both a claim for PrEP and a claim for RXC 1 within the benefit year. Operationally, to capture these cases, the adult enrollees with a PrEP prescription claim would receive the RXC 1 flag instead of the ACF only in cases where the enrollee has both a PrEP prescription claim and an HIV diagnosis but does not have a typical RXC 1 prescription claim because the enrollee did not begin treatment for HIV, or because their treatment medication was provided at no cost to the issuer and therefore no claim was submitted to EDGE. As such, a PrEP NDC's classification as RXC 1 or the ACF would be contingent on the presence of HCC 1 (HIV/AIDS) on an adult enrollee's record. We estimate that less than 2 percent of adult enrollees with a PrEP prescription claim would meet these criteria, and that such enrollees would account for less than 1 percent of enrollees receiving RXC 1. As such, the sample size of the PrEP ACF would remain high and the impact on the RXC 1 coefficient would be minimal. This approach to defining the hierarchical relationship between HCC 1, RXC 1, and the PrEP ACF would ensure that an adult enrollee with a PrEP prescription claim who later tested positive for HIV would have an increase in their risk score as a result of the additional diagnosis, satisfying Principles 4 (hierarchical factor definitions) and 5 (monotonicity). Although this approach would not be strictly consistent with mutually exclusive classification of diagnosis codes and NDCs into only one variable (Principle 6), we find this to be acceptable in this limited circumstance because it would precisely dictate which model factor an adult enrollee would receive (which satisfies the intent of Principle 6, mutually exclusive classification) and because PrEP medications can be part of an approved HIV treatment protocol when additional anti-retroviral drugs are used. Thus, it is not unreasonable to assume that the few adult enrollees with PrEP prescription claims and an HIV diagnosis are also receiving the additional medications needed to meet treatment requirements.[67]

Under the alternative approach, we would address the violation of monotonicity in the HHS risk adjustment adult models by placing the PrEP ACF below RXC 1 in a hierarchy but defining no hierarchical relationship between the PrEP ACF and HCC 1 (HIV/AIDS), allowing adult enrollees without RXC 1 to receive the PrEP ACF along with HCC 1 in cases where the enrollee has both a PrEP prescription claim and an HCC 1 diagnosis in their medical records for the benefit year. This approach would also ensure that an adult enrollee with a PrEP prescription claim who later tested positive for HIV would have an increase in their risk score as a result of the additional diagnosis, satisfying Principles 4 (hierarchical factor definitions) and 5 (monotonicity). This alternative PrEP ACF–RXC 1 hierarchy approach would likewise satisfy the intent of Principle 6 (mutually exclusive classification) by using similar considerations and filtering steps to those we currently use in our simulation of plan liability for PrEP. We solicit comments on addressing these hierarchy, monotonicity, and mutual exclusivity concerns, and both alternative approaches outlined above that are designed to address those concerns.

Table 2 below displays our testing of estimated values for the proposed PrEP ACF for the 2026 benefit year adult models using only 2021 benefit year enrollee-level EDGE data, but otherwise following the specifications of the 2025 benefit year HHS risk adjustment adult models.[68] We also included the values of the adult model factors that would likely be most impacted by the addition of a PrEP ACF to the 2026 benefit year risk adjustment models in table 2. This helps demonstrate whether the PrEP ACF would adhere to Principles 4, 5, and 6 described above. As indicated in the table, the addition of the adult model coefficients for a PrEP ACF (in each metal level) to the adult models would only minorly impact other coefficients, with the most impacted model coefficients being the age-sex coefficients for males between the ages of 25 and 44, RXC 1 (Anti-HIV Agents), and a small handful of other HCCs and RXCs. All impacts beyond those displayed in this table reflect absolute impacts on HHS risk adjustment adult model coefficient values of less than 0.01. However, we note that these values have not been subjected to either our normal modeling constraints, nor any of the constraints discussed in relation to Principles 4, 5 and 6.

[67] It is possible such medications may not appear in the enrollee-level EDGE data if the issuer cost is completely covered by rebates or other assistance. In such cases, the cost of the medication would not influence plan liability calculations and would not impact the coefficient of a PrEP ACF.

[68] For the specifications of the 2025 benefit year HHS risk adjustment adult and child models, including the Hepatitis C pricing adjustment and the list of factors included in the models, see the 2025 Payment Notice (89 FR 26238 through 26256).

TABLE 2: Estimated Unconstrained HHS Risk Adjustment Adult Model Factors for a PrEP ACF (ACF 01) and Other Adult Model Factors with Absolute Coefficient Impacts of at Least .01 When Adding a PrEP ACF to the Adult Models Using the 2021 Enrollee-Level EDGE Data

Metal Level	HCC/RXC/ACF Number	Factor	Estimated Model Coefficient	Estimated Coefficient Change Relative to Model Without PrEP ACF*
Platinum	*ACF 01*	*HIV Pre-Exposure Prophylaxis*	*2.678*	*+2.678*
		Age 25-29, Male	0.203	-0.017
		Age 30-34, Male	0.236	-0.019
		Age 35-39, Male	0.256	-0.016
		Age 40-44, Male	0.290	-0.012
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.525	-0.014
	HCC004	Viral or Unspecified Meningitis	7.607	-0.013
	HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.551	-0.010
	HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.861	-0.010
	HCC090	Personality Disorders	0.685	-0.010
	RXC 01	Anti-HIV Agents	4.550	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.757	-0.039
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.827	+0.040
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.424	+0.015
Gold	*ACF 01*	*HIV Pre-Exposure Prophylaxis*	*2.618*	*+2.618*
		Age 25-29, Male	0.135	-0.016
		Age 30-34, Male	0.163	-0.018
		Age 35-39, Male	0.180	-0.015
		Age 40-44, Male	0.209	-0.011
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.438	-0.014
	HCC004	Viral or Unspecified Meningitis	7.512	-0.013

Metal Level	HCC/RXC/ACF Number	Factor	Estimated Model Coefficient	Estimated Coefficient Change Relative to Model Without PrEP ACF*
	HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.492	-0.010
	HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.772	-0.010
	HCC090	Personality Disorders	0.608	-0.011
	RXC 01	Anti-HIV Agents	4.092	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.235	-0.039
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.692	+0.039
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.489	+0.014
Silver	*ACF 01*	HIV Pre-Exposure Prophylaxis	2.553	+2.553
		Age 25-29, Male	0.089	-0.016
		Age 30-34, Male	0.111	-0.018
		Age 35-39, Male	0.123	-0.015
		Age 40-44, Male	0.147	-0.012
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.398	-0.013
	HCC004	Viral or Unspecified Meningitis	7.464	-0.013
	HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.691	-0.010
	HCC090	Personality Disorders	0.514	-0.011
	RXC 01	Anti-HIV Agents	3.798	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.190	-0.037
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.598	+0.038
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.573	+0.014
Bronze	*ACF 01*	*HIV Pre-Exposure Prophylaxis*	*2.495*	*+2.495*
		Age 25-29, Male	0.057	-0.015
		Age 30-34, Male	0.073	-0.018
		Age 35-39, Male	0.081	-0.014
		Age 40-44, Male	0.100	-0.011
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.331	-0.013

Metal Level	HCC/RXC/ACF Number	Factor	Estimated Model Coefficient	Estimated Coefficient Change Relative to Model Without PrEP ACF*
	HCC004	Viral or Unspecified Meningitis	7.380	-0.012
	HCC090	Personality Disorders	0.395	-0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.023	-0.036
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.472	+0.038
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.680	+0.014
Catastrophic	*ACF 01*	*HIV Pre-Exposure Prophylaxis*	*2.493*	*+2.493*
		Age 25-29, Male	0.056	-0.015
		Age 30-34, Male	0.072	-0.018
		Age 35-39, Male	0.079	-0.015
		Age 40-44, Male	0.099	-0.011
	HCC003	Central Nervous System Infections, Except Viral Meningitis	7.329	-0.013
	HCC004	Viral or Unspecified Meningitis	7.377	-0.013
	HCC090	Personality Disorders	0.391	-0.010
	RXC 01	Anti-HIV Agents	3.343	+0.010
	RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.022	-0.036
	RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.468	+0.038
	RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	37.687	+0.013

*For these estimates, for consistency with the estimated model coefficients, which were calculated using the 2021 enrollee-level EDGE data and 2025 benefit year risk adjustment model specifications, we estimated these coefficient changes by comparing the estimated model coefficients to the final 2025 benefit year HHS risk adjustment model coefficients for each metal level.

Table 3 below displays estimated values for the proposed PrEP ACF for the 2026 benefit year HHS risk adjustment child models using only 2021 benefit year enrollee-level EDGE data, but otherwise following the specifications of the 2025 benefit year HHS risk adjustment child models.[69] Unlike the adult models, for the HHS risk adjustment child models, our testing found there are no impacts greater than 0.01 to the unconstrained coefficients for other child model factors. In this analysis for the child models, the approximate value of the

[69] Ibid.

PrEP ACF coefficient for children for the 2026 benefit year would fall below the HCC 1 (HIV/AIDS) coefficient for each metal level,[70] affirming that the identified concerns over Principles 4, 5 and 6 among the HHS risk adjustment adult models do not apply to the HHS risk adjustment child models.

TABLE 3: Estimated Unconstrained HHS Risk Adjustment Child Model Factors for a PrEP ACF (ACF 01)

Metal Level	Estimated Model Coefficient for ACF 01
Platinum	1.304
Gold	1.263
Silver	1.214
Bronze	1.161
Catastrophic	1.160

Again, the above coefficient values in tables 2 and 3 have been calculated using the 2021 enrollee-level EDGE data only, with the 2025 benefit year HHS risk adjustment model specifications, and without our normal modeling constraints nor any of the constraints discussed in relation to Principles 4, 5 and 6. Although we anticipate that these values will change slightly when the modeling constraints and the 2026 benefit year risk adjustment model specifications are applied, if the proposed new PrEP ACF variable is added to the adult and child models, we believe these offer reliable estimates of the potential impact of the adoption of the proposed new PrEP ACF variable on other factors and approximate values for the proposed draft new PrEP ACF coefficients for the adult and child models. If this proposal is finalized, the final coefficients will be made available in the final rule or through subsequent notice-and-comment rulemaking or guidance, as appropriate.

We solicit comments on our proposal to create a new ACF category of model factors for incorporation into the HHS risk adjustment models to account for unique medical expenses or services (such as PrEP) that do not meet the criteria to qualify as HCC or RXC factors, but impact the actuarial risk presented to issuers of risk adjustment covered plans. In addition, we solicit comments on our proposal to modify the treatment of PrEP in the HHS risk adjustment adult and child models beginning with the 2026 benefit year, as well as how to methodologically define a potential ACF category of model factors that accounts for PrEP (or other unique medical expenses or services) and what other considerations should be part of the analysis and modeling for this proposed new category of model factors (such as the availability of drug rebates [71] or differences in medication adherence for PrEP). Furthermore, we solicit comments regarding the principles to guide inclusion of potential ACF factors and the discussed alternative approaches for defining a PrEP ACF's hierarchical relationship to HCC 1 and RXC1 to address the concerns related to hierarchical factor definitions (Principle 4), violations of monotonicity (Principle 5), and violations of mutually exclusive classification (Principle 6) in the HHS risk adjustment adult models. Additionally, we solicit comments on whether generic versions of PrEP medication should be excluded from the definition of the proposed ACF for PrEP. Lastly, we solicit comments concerning whether there are any similar medical expenses or services that we should consider for potential new ACFs alongside PrEP.

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

The proposed 2026 benefit year HHS risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2020, 2021, and 2022 enrollee-level EDGE data are shown in tables 4 through 9.[72] The HHS risk adjustment 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.[73] Table 4 contains proposed factors for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 5 contains the proposed factors for each child model, including the age-sex, HCCs, and interacted HCC counts coefficients.[74] Table 6 lists the proposed HCCs selected for the interacted HCC counts factors that would apply to the HHS risk adjustment adult and child models. Table 7 contains the proposed factors for each HHS risk adjustment infant model. Tables 8 and 9 contain the HCCs included in the HHS risk adjustment infant models' maturity and severity categories, respectively.

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[70] As compared to the HCC 1 coefficients in table 5.

[71] For example, we believe there are likely substantial rebates for Descovy that are not captured in issuers' EDGE data submissions. See, for example, Dickson, S., Gabriel, N., and Hernandez, I. Estimated changes in price discounts for tenofovir-inclusive HIV treatments following introduction of tenofovir alafenamide. AIDS. 2022 Dec 1;36(15):2225–2227. doi: 10.1097/QAD.0000000000003401. See, also, Krakower, D. and Marcus, J.L. Commercial Determinants of Access to HIV Preexposure Prophylaxis. *JAMA Network Open.* 2023;6(11):e2342759. doi:*10.1001/jamanetworkopen.2023.42759.* See, also, McManus, K.A., et al. Geographic Variation in Qualified Health Plan Coverage and Prior Authorization Requirements for HIV Preexposure Prophylaxis. *JAMA Network Open.* 2023;6(11):e2342781. doi:*10.1001/jamanetworkopen.2023.42781.*

[72] See, supra, note 36.

[73] As finalized in the 2020 Payment Notice (84 FR 17466 through 17468), we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking. We are not proposing changes to the high-cost risk pool parameters for the 2026 benefit year. Therefore, we will maintain the $1 million threshold and 60 percent coinsurance rate for the 2026 benefit year.

[74] See, supra, note 36.

TABLE 4: Proposed Adult HHS Risk Adjustment Model Factors for the 2026 Benefit Year

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21-24, Male	0.196	0.136	0.096	0.068	0.063
	Age 25-29, Male	0.208	0.144	0.100	0.070	0.064
	Age 30-34, Male	0.240	0.171	0.122	0.086	0.079
	Age 35-39, Male	0.258	0.185	0.131	0.091	0.083
	Age 40-44, Male	0.288	0.210	0.152	0.107	0.098
	Age 45-49, Male	0.322	0.241	0.179	0.131	0.122
	Age 50-54, Male	0.381	0.293	0.225	0.171	0.160
	Age 55-59, Male	0.423	0.328	0.255	0.196	0.185
	Age 60-64, Male	0.466	0.363	0.283	0.217	0.204
	Age 21-24, Female	0.285	0.199	0.131	0.083	0.073
	Age 25-29, Female	0.312	0.218	0.144	0.090	0.078
	Age 30-34, Female	0.377	0.278	0.199	0.139	0.126
	Age 35-39, Female	0.428	0.326	0.245	0.181	0.169
	Age 40-44, Female	0.478	0.372	0.287	0.217	0.203
	Age 45-49, Female	0.483	0.375	0.287	0.213	0.199
	Age 50-54, Female	0.508	0.397	0.305	0.228	0.212
	Age 55-59, Female	0.469	0.359	0.267	0.192	0.176
	Age 60-64, Female	0.459	0.347	0.253	0.177	0.161
Diagnosis Factors						
HCC001	HIV/AIDS	0.324	0.249	0.214	0.184	0.182
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	8.769	8.567	8.520	8.428	8.425
HCC003	Central Nervous System Infections, Except Viral Meningitis	7.904	7.806	7.760	7.687	7.675
HCC004	Viral or Unspecified Meningitis	7.686	7.583	7.533	7.454	7.442
HCC006	Opportunistic Infections	8.506	8.456	8.403	8.327	8.309
HCC008	Metastatic Cancer	22.556	22.165	22.139	22.021	22.026
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	12.532	12.260	12.214	12.096	12.090
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors	5.519	5.346	5.280	5.167	5.154
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.718	3.537	3.464	3.342	3.327
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	2.399	2.267	2.201	2.101	2.087
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	0.972	0.882	0.795	0.690	0.671
HCC018	Pancreas Transplant Status	6.001	6.000	6.012	6.016	6.008
HCC019	Diabetes with Acute Complications	0.224	0.182	0.141	0.101	0.093
HCC020	Diabetes with Chronic Complications	0.224	0.182	0.141	0.101	0.093
HCC021	Diabetes without Complication	0.224	0.182	0.141	0.101	0.093
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19-21	0.224	0.200	0.163	0.098	0.083
HCC023	Protein-Calorie Malnutrition	10.678	10.559	10.519	10.449	10.441
HCC026	Mucopolysaccharidosis	21.504	21.326	21.298	21.232	21.231
HCC027	Lipidoses and Glycogenosis	21.504	21.326	21.298	21.232	21.231
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	6.053	5.953	5.914	5.848	5.839

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	1.277	1.204	1.153	1.080	1.067
HCC034	Liver Transplant Status/Complications	5.771	5.833	5.891	5.973	5.986
HCC035_1[a]	Acute Liver Failure/Disease, Including Neonatal Hepatitis	7.001	6.815	6.775	6.699	6.700
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	2.215	2.052	2.012	1.928	1.922
HCC036	Cirrhosis of Liver	0.668	0.588	0.546	0.478	0.467
HCC037_1	Chronic Viral Hepatitis C	0.540	0.480	0.432	0.378	0.371
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.540	0.480	0.432	0.378	0.371
HCC041	Intestine Transplant Status/Complications	5.771	5.833	5.891	5.973	5.986
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	10.677	10.534	10.530	10.490	10.492
HCC045	Intestinal Obstruction	4.906	4.701	4.639	4.517	4.506
HCC046	Chronic Pancreatitis	2.255	2.087	2.037	1.945	1.939
HCC047	Acute Pancreatitis	2.255	2.087	2.032	1.922	1.913
HCC048	Inflammatory Bowel Disease	1.988	1.892	1.814	1.689	1.663
HCC054	Necrotizing Fasciitis	7.354	7.204	7.177	7.119	7.116
HCC055	Bone/Joint/Muscle Infections/Necrosis	4.337	4.167	4.140	4.077	4.077
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	1.220	1.126	1.067	0.987	0.974
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.361	0.295	0.220	0.124	0.104
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	1.743	1.623	1.560	1.460	1.446
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	1.743	1.623	1.560	1.460	1.446
HCC063	Cleft Lip/Cleft Palate	0.716	0.616	0.552	0.467	0.454
HCC066	Hemophilia	73.949	73.659	73.629	73.537	73.541
HCC067	Myelodysplastic Syndromes and Myelofibrosis	10.804	10.680	10.652	10.586	10.578
HCC068	Aplastic Anemia	10.804	10.680	10.652	10.586	10.578
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	10.804	10.680	10.652	10.586	10.578
HCC070	Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero	1.693	1.605	1.548	1.476	1.465
HCC071	Sickle-Cell Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major	1.653	1.584	1.538	1.476	1.465
HCC073	Combined and Other Severe Immunodeficiencies	4.305	4.215	4.189	4.135	4.128
HCC074	Disorders of the Immune Mechanism	4.305	4.215	4.189	4.135	4.128
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.134	2.053	2.005	1.934	1.922
HCC081	Drug Use with Psychotic Complications	1.503	1.376	1.284	1.151	1.126
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	1.503	1.376	1.284	1.151	1.126
HCC083	Alcohol Use with Psychotic Complications	0.863	0.751	0.678	0.575	0.558
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	0.863	0.751	0.678	0.575	0.558

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC087_1	Schizophrenia	2.220	2.055	1.974	1.849	1.834
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	2.107	1.948	1.863	1.725	1.705
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders	0.929	0.834	0.750	0.640	0.619
HCC090	Personality Disorders	0.643	0.569	0.479	0.372	0.348
HCC094	Anorexia/Bulimia Nervosa	1.901	1.797	1.730	1.627	1.610
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	9.086	9.059	9.029	8.993	8.981
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	0.819	0.758	0.713	0.655	0.644
HCC102	Autistic Disorder	0.684	0.610	0.524	0.431	0.411
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	0.643	0.569	0.479	0.372	0.348
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	9.269	9.111	9.058	8.961	8.951
HCC107	Quadriplegia	9.269	9.111	9.058	8.961	8.951
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	6.184	6.041	5.985	5.886	5.874
HCC109	Paraplegia	6.184	6.041	5.985	5.886	5.874
HCC110	Spinal Cord Disorders/Injuries	4.886	4.708	4.657	4.554	4.544
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	4.966	4.824	4.756	4.643	4.627
HCC112	Quadriplegic Cerebral Palsy	0.612	0.524	0.458	0.364	0.347
HCC113	Cerebral Palsy, Except Quadriplegic	0.339	0.274	0.220	0.148	0.134
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.165	1.083	1.027	0.938	0.921
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.056	4.973	4.956	4.917	4.915
HCC117	Muscular Dystrophy	1.328	1.239	1.173	1.079	1.062
HCC118	Multiple Sclerosis	2.666	2.536	2.479	2.383	2.370
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	1.328	1.239	1.173	1.079	1.062
HCC120	Seizure Disorders and Convulsions	0.940	0.850	0.787	0.696	0.681
HCC121	Hydrocephalus	9.454	9.362	9.314	9.244	9.232
HCC122	Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage	9.882	9.748	9.694	9.603	9.590
HCC123	Narcolepsy and Cataplexy	4.531	4.404	4.343	4.247	4.233
HCC125	Respirator Dependence/Tracheostomy Status	21.608	21.401	21.360	21.273	21.271
HCC126	Respiratory Arrest	8.172	7.957	7.913	7.823	7.821
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	8.172	7.957	7.913	7.823	7.821
HCC128	Heart Assistive Device/Artificial Heart	15.142	15.048	15.018	14.981	14.985
HCC129	Heart Transplant Status/Complications	15.142	15.048	15.018	14.981	14.985
HCC130	Heart Failure	1.769	1.684	1.647	1.582	1.572
HCC131	Acute Myocardial Infarction	4.648	4.428	4.402	4.328	4.331

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	3.381	3.185	3.139	3.036	3.030
HCC135	Heart Infection/Inflammation, Except Rheumatic	8.377	8.292	8.237	8.153	8.137
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	2.031	1.943	1.886	1.810	1.798
HCC138	Major Congenital Heart/Circulatory Disorders	2.031	1.943	1.886	1.810	1.798
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	2.031	1.943	1.886	1.810	1.798
HCC142	Specified Heart Arrhythmias	1.828	1.726	1.660	1.556	1.536
HCC145	Intracranial Hemorrhage	10.183	10.022	9.976	9.889	9.882
HCC146	Ischemic or Unspecified Stroke	1.382	1.269	1.232	1.160	1.153
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.096	1.979	1.920	1.819	1.803
HCC150	Hemiplegia/Hemiparesis	2.952	2.831	2.813	2.765	2.766
HCC151	Monoplegia, Other Paralytic Syndromes	2.464	2.353	2.306	2.226	2.217
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	7.862	7.701	7.708	7.682	7.691
HCC154	Vascular Disease with Complications	4.946	4.803	4.760	4.678	4.670
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	7.348	7.269	7.200	7.095	7.071
HCC158	Lung Transplant Status/Complications	11.134	11.054	11.027	10.996	11.000
HCC159	Cystic Fibrosis	3.817	3.697	3.645	3.565	3.555
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.620	0.546	0.472	0.381	0.363
HCC161_1	Severe Asthma	0.620	0.546	0.472	0.381	0.363
HCC161_2	Asthma, Except Severe	0.620	0.546	0.472	0.381	0.363
HCC162	Fibrosis of Lung and Other Lung Disorders	1.544	1.465	1.411	1.329	1.314
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	7.234	7.126	7.082	7.011	7.001
HCC174	Exudative Macular Degeneration	1.162	1.038	0.948	0.814	0.793
HCC183	Kidney Transplant Status/Complications	6.001	6.000	6.012	6.016	6.008
HCC184	End Stage Renal Disease	19.250	18.854	18.967	18.808	18.721
HCC187	Chronic Kidney Disease, Stage 5	0.723	0.649	0.643	0.605	0.594
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.723	0.649	0.643	0.605	0.594
HCC203	Ectopic and Molar Pregnancy	1.579	1.424	1.295	1.099	1.065
HCC204	Miscarriage with Complications	0.605	0.530	0.412	0.252	0.210
HCC205	Miscarriage with No or Minor Complications	0.605	0.530	0.412	0.252	0.210
HCC207	Pregnancy with Delivery with Major Complications	3.611	3.337	3.146	2.824	2.782
HCC208	Pregnancy with Delivery with Complications	3.611	3.337	3.146	2.824	2.782
HCC209	Pregnancy with Delivery with No or Minor Complications	2.666	2.465	2.249	1.883	1.811
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications	0.695	0.606	0.465	0.292	0.252
HCC211	(Ongoing) Pregnancy without Delivery with Complications	0.464	0.395	0.270	0.138	0.107

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.011	0.000	0.000	0.000	0.000
HCC217	Chronic Ulcer of Skin, Except Pressure	1.442	1.349	1.315	1.257	1.251
HCC218	Extensive Third-Degree Burns	25.026	24.830	24.788	24.706	24.701
HCC219	Major Skin Burn or Condition	2.495	2.374	2.316	2.230	2.220
HCC223	Severe Head Injury	17.509	17.362	17.298	17.192	17.176
HCC226	Hip and Pelvic Fractures	7.706	7.461	7.433	7.349	7.351
HCC228	Vertebral Fractures without Spinal Cord Injury	4.015	3.856	3.784	3.662	3.646
HCC234	Traumatic Amputations and Amputation Complications	4.454	4.299	4.273	4.209	4.208
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	18.843	18.873	18.850	18.846	18.843
HCC253	Artificial Openings for Feeding or Elimination	5.485	5.366	5.341	5.287	5.284
HCC254	Amputation Status, Upper Limb or Lower Limb	0.862	0.766	0.731	0.669	0.663
Interacted HCC Counts Factors						
	Severe illness, 1 payment HCC	-5.771	-5.833	-5.891	-5.973	-5.986
	Severe illness, 2 payment HCCs	-5.615	-5.693	-5.729	-5.792	-5.798
	Severe illness, 3 payment HCCs	-4.802	-4.863	-4.817	-4.790	-4.774
	Severe illness, 4 payment HCCs	-4.155	-4.159	-4.030	-3.889	-3.848
	Severe illness, 5 payment HCCs	-3.519	-3.451	-3.251	-3.011	-2.952
	Severe illness, 6 payment HCCs	-3.161	-2.997	-2.734	-2.401	-2.328
	Severe illness, 7 payment HCCs	-2.535	-2.249	-1.923	-1.504	-1.419
	Severe illness, 8 payment HCCs	-2.261	-1.896	-1.537	-1.036	-0.942
	Severe illness, 9 payment HCCs	-0.347	0.162	0.579	1.162	1.267
	Severe illness, 10 or more payment HCCs	6.494	7.367	7.904	8.706	8.837
	Transplant severe illness, 4 payment HCCs	3.479	3.363	3.296	3.168	3.138
	Transplant severe illness, 5 payment HCCs	6.565	6.435	6.380	6.259	6.233
	Transplant severe illness, 6 payment HCCs	10.720	10.578	10.529	10.408	10.380
	Transplant severe illness, 7 payment HCCs	14.798	14.641	14.590	14.473	14.448
	Transplant severe illness, 8 or more payment HCCs	30.301	30.241	30.218	30.135	30.110
Enrollment Duration Factors						
	Enrolled for 1 month, at least one payment HCC	11.551	10.110	9.201	8.280	8.111
	Enrolled for 2 months, at least one payment HCC	5.271	4.545	4.055	3.588	3.505
	Enrolled for 3 months, at least one payment HCC	3.355	2.883	2.542	2.223	2.168
	Enrolled for 4 months, at least one payment HCC	2.108	1.785	1.538	1.312	1.272
	Enrolled for 5 months, at least one payment HCC	1.583	1.343	1.152	0.975	0.942
	Enrolled for 6 months, at least one payment HCC	1.014	0.837	0.689	0.548	0.521
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	5.080	4.590	4.301	3.855	3.786
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents	8.273	7.797	7.762	7.644	7.662

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 03[b]	Antiarrhythmics	0.070	0.063	0.056	0.046	0.046
RXC 04	Phosphate Binders	0.920	1.051	0.885	1.053	1.217
RXC 05	Inflammatory Bowel Disease Agents	1.213	1.149	1.062	0.957	0.932
RXC 06	Insulin	1.345	1.183	1.021	0.860	0.827
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.862	0.761	0.637	0.457	0.417
RXC 08	Multiple Sclerosis Agents	14.243	13.511	13.322	12.953	12.903
RXC 09	Immune Suppressants and Immunomodulators	11.920	11.394	11.363	11.214	11.227
RXC 10	Cystic Fibrosis Agents	20.797	20.324	20.299	20.170	20.180
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001	2.337	2.374	2.650	2.960	3.040
RXC 02 x HCC037_1, 036, 035_2, 035_1, 034	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034)	-0.540	-0.480	-0.432	-0.378	-0.371
RXC 03 x HCC142	Additional effect for enrollees with RXC 03 and HCC 142	0.000	0.000	0.000	0.000	0.000
RXC 04 x HCC184, 183, 187, 188	Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188)	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041)	-0.868	-0.830	-0.781	-0.706	-0.690
RXC 06 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021)	0.398	0.430	0.501	0.497	0.503
RXC 07 x HCC018, 019, 020, 021	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021)	-0.224	-0.181	-0.141	-0.101	-0.093
RXC 08 x HCC118	Additional effect for enrollees with RXC 08 and HCC 118	-0.686	-0.368	-0.134	0.196	0.274
RXC 09 x HCC056 or 057 and 048 or 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057)	0.441	0.500	0.552	0.628	0.644
RXC 09 x HCC056	Additional effect for enrollees with RXC 09 and HCC 056	-1.220	-1.126	-1.067	-0.987	-0.974
RXC 09 x HCC057	Additional effect for enrollees with RXC 09 and HCC 057	-0.361	-0.295	-0.220	-0.124	-0.104
RXC 09 x HCC048, 041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041)	-0.104	-0.015	0.050	0.151	0.171
RXC 10 x HCC159, 158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158)	42.842	42.900	42.986	43.095	43.118

a/ 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.

b/ We constrain RXC 03 to be equal to average plan liability for RXC 03 drugs, RXC 04 to be equal to the average plan liability for RXC 04 drugs, and we constrain RXC 03 x HCC142 and RXC 04 x HCC184, 183, 187, 188 to be equal to 0. See *March 2016 Risk Adjustment Methodology 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 (where we previously discussed the use of constraints in the HHS risk adjustment models).

TABLE 5: Proposed Child HHS Risk Adjustment Model Factors for the 2026 Benefit Year

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2-4, Male	0.275	0.197	0.147	0.110	0.103
Age 5-9, Male	0.206	0.139	0.100	0.076	0.071
Age 10-14, Male	0.218	0.153	0.113	0.089	0.085
Age 15-20, Male	0.254	0.183	0.135	0.102	0.096
Age 2-4, Female	0.222	0.152	0.112	0.087	0.081
Age 5-9, Female	0.153	0.090	0.058	0.040	0.036
Age 10-14, Female	0.221	0.155	0.115	0.091	0.088
Age 15-20, Female	0.286	0.200	0.136	0.090	0.081
Diagnosis Factors					
HIV/AIDS	4.432	4.020	3.933	3.744	3.737
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	15.159	14.969	14.894	14.777	14.766
Central Nervous System Infections, Except Viral Meningitis	14.258	14.125	14.065	13.983	13.972
Viral or Unspecified Meningitis	13.861	13.735	13.667	13.575	13.559
Opportunistic Infections	19.550	19.503	19.430	19.350	19.333
Metastatic Cancer	31.112	30.879	30.817	30.711	30.704
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.342	9.119	9.022	8.874	8.855
Non-Hodgkin Lymphomas and Other Cancers and Tumors	8.439	8.247	8.142	7.988	7.963
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	4.086	3.946	3.864	3.740	3.716
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	4.086	3.946	3.864	3.740	3.716
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.309	1.199	1.105	0.987	0.963
Pancreas Transplant Status	12.114	12.103	12.087	12.074	12.069
Diabetes with Acute Complications	2.221	1.995	1.784	1.480	1.431
Diabetes with Chronic Complications	2.221	1.995	1.784	1.480	1.431
Diabetes without Complication	2.221	1.995	1.784	1.480	1.431
Protein-Calorie Malnutrition	19.116	19.000	18.960	18.905	18.898
Mucopolysaccharidosis	30.871	30.641	30.596	30.496	30.493
Lipidoses and Glycogenosis	30.871	30.641	30.596	30.496	30.493
Congenital Metabolic Disorders, Not Elsewhere Classified	4.743	4.634	4.577	4.500	4.489
Amyloidosis, Porphyria, and Other Metabolic Disorders	4.743	4.634	4.577	4.500	4.489
Adrenal, Pituitary, and Other Significant Endocrine Disorders	5.040	4.820	4.751	4.645	4.637
Liver Transplant Status/Complications	12.114	12.103	12.087	12.074	12.069
Acute Liver Failure/Disease, Including Neonatal Hepatitis	9.374	9.241	9.203	9.132	9.121
Chronic Liver Failure/End-Stage Liver Disorders	7.833	7.686	7.638	7.549	7.536
Cirrhosis of Liver	3.898	3.779	3.716	3.629	3.614
Chronic Viral Hepatitis C	1.186	1.081	1.008	0.923	0.907
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.473	0.401	0.326	0.239	0.218

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Intestine Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	18.316	18.056	18.004	17.906	17.903
Intestinal Obstruction	4.523	4.352	4.262	4.128	4.109
Chronic Pancreatitis	8.313	8.165	8.114	8.016	8.002
Acute Pancreatitis	6.026	5.805	5.717	5.565	5.546
Inflammatory Bowel Disease	10.352	9.970	9.879	9.690	9.676
Necrotizing Fasciitis	4.288	4.095	4.002	3.869	3.852
Bone/Joint/Muscle Infections/Necrosis	4.288	4.095	4.002	3.869	3.852
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.773	4.527	4.447	4.318	4.307
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.975	0.876	0.784	0.672	0.650
Osteogenesis Imperfecta and Other Osteodystrophies	1.213	1.112	1.041	0.953	0.939
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.213	1.112	1.041	0.953	0.939
Cleft Lip/Cleft Palate	0.884	0.761	0.665	0.541	0.519
Hemophilia	62.038	61.611	61.536	61.361	61.352
Myelodysplastic Syndromes and Myelofibrosis	12.776	12.620	12.565	12.477	12.468
Aplastic Anemia	12.776	12.620	12.565	12.477	12.468
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	12.776	12.620	12.565	12.477	12.468
Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero[8]	3.334	3.185	3.102	2.992	2.974
Sickle-Cell Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major	3.334	3.185	3.102	2.992	2.974
Combined and Other Severe Immunodeficiencies	5.418	5.282	5.226	5.136	5.125
Disorders of the Immune Mechanism	5.418	5.282	5.226	5.136	5.125
Coagulation Defects and Other Specified Hematological Disorders	3.928	3.824	3.756	3.667	3.652
Drug Use with Psychotic Complications	2.337	2.195	2.104	1.972	1.949
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.337	2.195	2.104	1.972	1.949
Alcohol Use with Psychotic Complications	0.778	0.650	0.545	0.397	0.373
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	0.778	0.650	0.545	0.397	0.373
Schizophrenia	3.540	3.296	3.177	2.995	2.970
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.132	2.909	2.778	2.582	2.553
Major Depressive Disorder, Severe, and Bipolar Disorders	2.588	2.398	2.271	2.101	2.073
Personality Disorders	0.458	0.375	0.273	0.158	0.133
Anorexia/Bulimia Nervosa	2.173	2.039	1.948	1.821	1.798
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	12.591	12.534	12.493	12.442	12.431
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	0.870	0.763	0.692	0.590	0.572
Autistic Disorder	2.588	2.398	2.271	2.101	2.073
Pervasive Developmental Disorders, Except Autistic Disorder	0.484	0.414	0.333	0.251	0.234
Traumatic Complete Lesion Cervical Spinal Cord	10.809	10.632	10.574	10.475	10.467
Quadriplegia	10.809	10.632	10.574	10.475	10.467

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Traumatic Complete Lesion Dorsal Spinal Cord	9.868	9.650	9.591	9.476	9.466
Paraplegia	9.868	9.650	9.591	9.476	9.466
Spinal Cord Disorders/Injuries	4.587	4.409	4.306	4.146	4.118
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	45.490	45.226	45.175	45.069	45.058
Quadriplegic Cerebral Palsy	0.831	0.651	0.579	0.461	0.449
Cerebral Palsy, Except Quadriplegic	0.381	0.266	0.204	0.124	0.109
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.523	1.414	1.350	1.252	1.237
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.844	10.706	10.684	10.631	10.630
Muscular Dystrophy	5.690	5.547	5.476	5.366	5.349
Multiple Sclerosis	7.657	7.323	7.253	7.109	7.103
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	5.690	5.547	5.476	5.366	5.349
Seizure Disorders and Convulsions	1.475	1.352	1.242	1.102	1.074
Hydrocephalus	12.442	12.383	12.338	12.292	12.280
Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic Brain Compression/Anoxic Damage	11.881	11.883	11.873	11.873	11.870
Narcolepsy and Cataplexy	4.158	4.015	3.919	3.783	3.752
Respirator Dependence/Tracheostomy Status	25.819	25.590	25.527	25.420	25.412
Respiratory Arrest	15.588	15.336	15.257	15.114	15.103
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	15.588	15.336	15.257	15.114	15.103
Heart Assistive Device/Artificial Heart	14.935	14.859	14.793	14.709	14.693
Heart Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Heart Failure	3.788	3.690	3.638	3.557	3.542
Acute Myocardial Infarction	1.293	1.229	1.179	1.104	1.091
Unstable Angina and Other Acute Ischemic Heart Disease	1.293	1.229	1.179	1.104	1.091
Heart Infection/Inflammation, Except Rheumatic	15.964	15.860	15.788	15.694	15.675
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	3.733	3.594	3.485	3.351	3.326
Major Congenital Heart/Circulatory Disorders	0.957	0.868	0.769	0.670	0.651
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.487	0.406	0.327	0.251	0.238
Specified Heart Arrhythmias	3.007	2.866	2.784	2.671	2.654
Intracranial Hemorrhage	12.917	12.857	12.829	12.790	12.784
Ischemic or Unspecified Stroke	1.196	1.087	1.028	0.938	0.926
Cerebral Aneurysm and Arteriovenous Malformation	0.788	0.690	0.638	0.553	0.537
Hemiplegia/Hemiparesis	5.113	4.995	4.936	4.846	4.836
Monoplegia, Other Paralytic Syndromes	2.053	1.940	1.874	1.773	1.757
Atherosclerosis of the Extremities with Ulceration or Gangrene	10.494	10.279	10.205	10.071	10.061
Vascular Disease with Complications	10.563	10.421	10.369	10.279	10.271
Pulmonary Embolism and Deep Vein Thrombosis	20.314	20.192	20.129	20.039	20.025
Lung Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Cystic Fibrosis	51.368	50.854	50.808	50.658	50.665
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.574	1.429	1.324	1.188	1.165

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Severe Asthma	1.300	1.150	1.025	0.871	0.843
Asthma, Except Severe	0.315	0.248	0.171	0.105	0.091
Fibrosis of Lung and Other Lung Disorders	1.467	1.341	1.229	1.097	1.072
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	11.748	11.771	11.801	11.852	11.859
Kidney Transplant Status/Complications	12.114	12.103	12.087	12.074	12.069
End Stage Renal Disease	25.623	25.420	25.403	25.337	25.332
Chronic Kidney Disease, Stage 5	0.853	0.779	0.729	0.672	0.665
Chronic Kidney Disease, Severe (Stage 4)	0.853	0.779	0.729	0.672	0.665
Ectopic and Molar Pregnancy	0.755	0.625	0.472	0.330	0.308
Miscarriage with Complications	0.389	0.294	0.158	0.035	0.011
Miscarriage with No or Minor Complications	0.389	0.294	0.158	0.035	0.011
Pregnancy with Delivery with Major Complications	3.064	2.797	2.554	2.151	2.065
Pregnancy with Delivery with Complications	3.064	2.797	2.554	2.151	2.065
Pregnancy with Delivery with No or Minor Complications	2.183	1.985	1.734	1.324	1.218
(Ongoing) Pregnancy without Delivery with Major Complications	0.420	0.308	0.145	0.014	0.000
(Ongoing) Pregnancy without Delivery with Complications	0.420	0.308	0.145	0.014	0.000
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.210	0.128	0.027	0.000	0.000
Chronic Ulcer of Skin, Except Pressure	2.287	2.195	2.121	2.041	2.027
Extensive Third-Degree Burns	22.632	22.402	22.326	22.204	22.186
Major Skin Burn or Condition	2.587	2.430	2.328	2.189	2.168
Severe Head Injury	22.632	22.402	22.326	22.204	22.186
Hip and Pelvic Fractures	4.602	4.393	4.289	4.153	4.136
Vertebral Fractures without Spinal Cord Injury	4.311	4.117	4.000	3.829	3.802
Traumatic Amputations and Amputation Complications	4.308	4.125	4.026	3.865	3.835
Stem Cell, Including Bone Marrow, Transplant Status/Complications	14.935	14.859	14.793	14.709	14.693
Artificial Openings for Feeding or Elimination	5.156	4.991	4.958	4.879	4.875
Amputation Status, Upper Limb or Lower Limb	4.308	4.125	4.026	3.865	3.835
Interacted HCC Counts Factors					
Severe illness, 1 payment HCC	-11.721	-11.771	-11.801	-11.852	-11.859
Severe illness, 2 payment HCCs	-11.721	-11.771	-11.801	-11.852	-11.859
Severe illness, 3 payment HCCs	-10.550	-10.621	-10.563	-10.542	-10.525
Severe illness, 4 payment HCCs	-9.240	-9.248	-9.085	-8.937	-8.892
Severe illness, 5 payment HCCs	-8.082	-8.043	-7.823	-7.606	-7.548
Severe illness, 6 or 7 payment HCCs	-3.581	-3.360	-3.017	-2.629	-2.542
Severe illness, 8 or more payment HCCs	16.144	16.838	17.409	18.129	18.259
Transplant severe illness, 4 or more payment HCCs	13.212	13.245	13.253	13.269	13.271

TABLE 6: Proposed HCCs Selected for the HCC Interacted Counts Variables for the HHS Risk Adjustment Adult and Child Models for the 2026 Benefit Year

Payment HCC	Severity Illness Indicator	Transplant Indicator
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 Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic 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 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
G24 (Includes HCC 18 Pancreas Transplant Status and HCC 183 Kidney Transplant Status/Complications)	X	X

TABLE 7: Proposed Infant HHS Risk Adjustment Model Factors for the 2026 Benefit Year

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	202.124	200.721	200.443	199.930	199.923
Extremely Immature * Severity Level 4	135.710	134.101	133.672	132.966	132.922
Extremely Immature * Severity Level 3	31.009	29.686	29.283	28.690	28.647
Extremely Immature * Severity Level 2	31.009	29.686	29.283	28.690	28.647
Extremely Immature * Severity Level 1 (Lowest)	31.009	29.686	29.283	28.690	28.647
Immature * Severity Level 5 (Highest)	129.458	128.096	127.837	127.350	127.343
Immature * Severity Level 4	68.163	66.651	66.320	65.727	65.699
Immature * Severity Level 3	31.009	29.686	29.283	28.690	28.647
Immature * Severity Level 2	26.411	25.209	24.810	24.230	24.181
Immature * Severity Level 1 (Lowest)	23.143	21.917	21.486	20.866	20.806
Premature/Multiples * Severity Level 5 (Highest)	110.758	109.418	109.135	108.626	108.606
Premature/Multiples * Severity Level 4	28.791	27.494	27.114	26.514	26.473
Premature/Multiples * Severity Level 3	12.969	12.062	11.572	10.902	10.797
Premature/Multiples * Severity Level 2	7.878	7.175	6.664	5.992	5.863
Premature/Multiples * Severity Level 1 (Lowest)	5.519	4.934	4.429	3.846	3.726
Term * Severity Level 5 (Highest)	81.499	80.353	80.008	79.461	79.415
Term * Severity Level 4	16.505	15.543	15.080	14.433	14.351
Term * Severity Level 3	5.467	4.914	4.413	3.825	3.702
Term * Severity Level 2	3.655	3.183	2.680	2.112	1.991
Term * Severity Level 1 (Lowest)	1.955	1.593	1.156	0.813	0.752
Age1 * Severity Level 5 (Highest)	67.661	66.998	66.818	66.533	66.516
Age1 * Severity Level 4	12.321	11.828	11.591	11.279	11.240
Age1 * Severity Level 3	2.767	2.515	2.325	2.133	2.100
Age1 * Severity Level 2	1.792	1.572	1.374	1.176	1.136
Age1 * Severity Level 1 (Lowest)	0.576	0.485	0.431	0.396	0.389
Age 0 Male	0.606	0.569	0.541	0.484	0.471
Age 1 Male	0.074	0.060	0.044	0.025	0.021

TABLE 8: Proposed HHS HCCs Included in HHS Risk Adjustment Infant Model Maturity Categories for 2026 Benefit Year

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 9: Proposed HHS HCCs Included in HHS Risk Adjustment Infant Model Severity Categories for 2026 Benefit Year

Severity Category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer
Severity Level 5	Pancreas Transplant Status
Severity Level 5	Liver Transplant Status/Complications
Severity Level 5	Intestine Transplant Status/Complications
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis
Severity Level 5	Respirator Dependence/Tracheostomy Status
Severity Level 5	Heart Assistive Device/Artificial Heart
Severity Level 5	Heart Transplant Status/Complications
Severity Level 5	Heart Failure
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders
Severity Level 5	Lung Transplant Status/Complications
Severity Level 5	Kidney Transplant Status/Complications
Severity Level 5	End Stage Renal Disease
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia
Severity Level 4	Mucopolysaccharidosis
Severity Level 4	Adrenal, Pituitary, and Other Significant Endocrine Disorders
Severity 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	Nontraumatic Coma, Except Diabetic, Hepatic, or Hypoglycemic; Nontraumatic 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 Category	HCC/Description
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	Sickle Cell Anemia (Hb-SS) and Thalassemia Beta Zero
Severity Level 3	Disorders of the Immune Mechanism
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders
Severity Level 3	Drug Use with Psychotic Complications
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications
Severity Level 3	Alcohol Use with Psychotic Complications
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord
Severity Level 3	Paraplegia
Severity Level 3	Spinal Cord Disorders/Injuries
Severity Level 3	Cerebral Palsy, Except Quadriplegic
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies
Severity Level 3	Muscular Dystrophy
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders
Severity Level 3	Hydrocephalus
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders
Severity 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 Category	HCC/Description
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 Disorders, Except Sickle-Cell Anemia (Hb-SS) and Thalassemia Beta Zero; Beta Thalassemia Major
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	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

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e. Cost-Sharing Reduction Adjustments

In the 2025 Payment Notice (89 FR 26252 through 26254), we finalized the updated CSR adjustment factors for American Indian/Alaska Native (AI/AN) zero-cost sharing and limited cost sharing CSR plan variant enrollees for the 2025 benefit year, and for all future benefit years, unless changed through notice-and-comment rulemaking. In the 2025 Payment Notice (89 FR 26252 through 26254), we also finalized maintaining the existing CSR adjustment factors for silver plan variant enrollees (70 percent, 73 percent, 87 percent, and 94 percent AV plan variants)[75] for the 2025 benefit year and beyond, unless changed through notice-and-comment rulemaking. Under this approach, we will no longer republish these factors in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed.

For the 2026 benefit year, we are not proposing to change the CSR adjustment factors as finalized in the 2025 Payment Notice and will maintain the existing CSR adjustment factors for the 2026 benefit year. Since we are not proposing any changes to the CSR adjustment factors for the 2026 benefit year, we are not republishing the CSR adjustment factors in this rule.[76]

f. Model Performance Statistics

Each benefit year, to evaluate the HHS risk adjustment model performance, we examine each model's R-squared statistic and predictive ratios (PRs). The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The PR 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 PR represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a PR of 1.0. For each of the current and proposed HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent HHS risk adjustment models.[77] Because we propose to blend the coefficients from separately solved models based on the 2020, 2021 and 2022 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 statistics for the proposed 2026 benefit HHS risk adjustment models are shown in table 10.

[75] See 83 FR 16930 at 16953; 84 FR 17478 through 17479; 85 FR 29190; 86 FR 24181; 87 FR 27235 through 27236; 88 FR 25772 through 25774; and 89 FR 26252 through 26254.

[76] See CSR adjustment factors finalized in the 2025 Payment Notice at 89 FR 26252 through 26254.

[77] Hileman, G., & Steele, S. (2016). *Accuracy of Claims-Based Risk Scoring Models.* Society of Actuaries. *https://www.soa.org/4937b5/globalassets/assets/files/research/research-2016-accuracy-claims-based-risk-scoring-models.pdf.*

TABLE 10: R-Squared Statistic for the Proposed 2026 HHS Risk Adjustment Models

Models	2020 Enrollee-Level EDGE Data	2021 Enrollee-Level EDGE Data	2022 Enrollee-Level EDGE Data
Platinum Adult	0.4377	0.4187	0.4067
Gold Adult	0.4317	0.4129	0.4007
Silver Adult	0.4293	0.4105	0.3980
Bronze Adult	0.4252	0.4063	0.3936
Catastrophic Adult	0.4246	0.4057	0.3928
Platinum Child	0.3453	0.3554	0.3620
Gold Child	0.3421	0.3526	0.3594
Silver Child	0.3401	0.3506	0.3574
Bronze Child	0.3371	0.3476	0.3544
Catastrophic Child	0.3365	0.3470	0.3537
Platinum Infant	0.2928	0.3072	0.2862
Gold Infant	0.2892	0.3037	0.2827
Silver Infant	0.2878	0.3023	0.2813
Bronze Infant	0.2856	0.3000	0.2790
Catastrophic Infant	0.2853	0.2997	0.2787

3. Overview of the HHS Risk Adjustment Methodology: State Payment Transfer Formula

In part 2 of the 2022 Payment Notice (86 FR 24183 through 24186), we finalized the proposal to continue to use the State payment transfer formula finalized in the 2021 Payment Notice for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. We explained that under this approach, we will no longer republish these formulas in future annual HHS notice of benefit and payment parameters rules unless changes are being proposed. We are not proposing any changes to the formula in this rule, and therefore, are not republishing the formulas in this rule. We therefore would continue to apply the formula as finalized in the 2021 Payment Notice (86 FR 24183 through 24186) in the States where HHS operates the risk adjustment program in the 2026 benefit year.

Additionally, as finalized in the 2020 Payment Notice (84 FR 17466 through 17468), we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking. We are not proposing any changes to the high-cost risk pool parameters for the 2025 benefit year; therefore, we would maintain the $1 million threshold and 60 percent coinsurance rate.[78]

[78] See 81 FR 94081. See also 84 FR 17467.

4. Solicitation of Comments—Time Value of Money in HHS-Operated Risk Adjustment Program

HHS received feedback from some interested parties that, for the 2023 benefit year, issuers of risk adjustment covered plans were impacted more by the time value of money, for the collection and remittance of State transfers that occurs 8 to 10 months after the conclusion of the benefit year,[79] than in any previous benefit years of the HHS-operated risk adjustment program. Given that interest rates were the highest in 2023 than in any year since the passage of the ACA, the impact of the time value of money has changed and is higher than it has been historically. We therefore solicit comments on what impact the time value of money may have on issuers' assessment of actuarial risk and incentives for adverse selection.

Unlike Medicare Advantage's risk adjustment program, under which CMS makes risk-adjusted monthly payments to Medicare Advantage organizations during the coverage year (in advance of each month of coverage) using interim risk scores and then does a reconciliation to updated risk scores after the final deadline for submission of all risk adjustment data, the HHS-operated risk adjustment program for the individual, small group and merged markets uses a final data submission deadline 4 months after the end of the benefit year and calculates issuers' plan liability risk scores and the State transfer amounts 2 months after that, resulting in State transfers being made 8 to 10 months after the end of the benefit year.[80] HHS typically announces State transfer amounts no later than June 30 of the year following the benefit year,[81] begins to collect charges in August of the year following the benefit year, and begins to make payments to issuers in the fall of the year following the applicable benefit year. This process means that issuers whose enrollees have higher-than-average actuarial risk do not receive their State transfer payments until the fall of the year following the benefit year. Over this same time period, issuers whose enrollees have lower-than-average actuarial risk are able to benefit from the availability of capital from the collection of premiums for

[79] Charges are typically sent out in August in the year after the benefit year and the majority of payments typically made in September and October in the year after the benefit year; payments held for sequestration from charges collected prior to October 1st are released in November of the same year.

[80] The EDGE data submission deadline is April 30, or if such date is not a business day, the next applicable business day. See 45 CFR 153.730. We note that the deadline for submission of 2023 benefit year data was extended to provide issuers flexibility in managing the challenges associated with the Change HealthCare cybersecurity incident and its impact on risk adjustment covered plans. See *CMS Announcement BY2023 EDGE Data Submission MLR Extension https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/by_2023_announcement_edge_data_submission_mlr_extension.pdf.*

[81] Risk adjustment transfer amounts are typically announced no later than June 30, or if such date is not a business day, the next applicable business day. See 45 CFR 153.310(e). The date for announcement of transfer amounts for the 2023 benefit year was extended in recognition of the extension of the deadline for EDGE data submissions. See supra note 92. After transfer amounts for a benefit year are announced, collection of charges typically begins in August with payments beginning in September.

investment that could accrue interest between the benefit year and when the collection of charges begins in August of the year following the benefit year, which we refer to as the ''time value of money.''

To continue to ensure appropriate incentives exist in the individual, small group, and merged markets to cover both healthy and sick enrollees, we believe that this market dynamic, the time value of money, and its potential impact on actuarial risk and adverse selection should be discussed and considered. Consistent with section 1343 of the ACA, in States where HHS is responsible for operating the program,[82] we calculate average actuarial risk to assess charges to issuers with risk adjustment covered plans with lower-than-average actuarial risk and to make payments to issuers with risk adjustment covered plans with higher-than-average actuarial risk. The ACA's permanent risk adjustment program for the individual, small group, and merged markets is intended to minimize the incentives for adverse selection, to help level the playing field between insurance companies, and to foster a stable market in which issuers provide coverage to individuals with higher health care costs and those who are sick have access to the coverage they need.

The impact of the time value of money has increased to levels significantly higher than those seen in the initial years after the passage of the ACA. For example, in January 2016, the annual short-term Applicable Federal Rate (AFR) interest rate was 0.75 percent, whereas in January 2023 the AFR interest rate had increased to 4.50 percent.[83] This increase in the time value of money could impact the individual, small group, and merged markets by changing the incentives faced by issuers enrolling lower-than-average risk populations rather than higher-than-average risk populations, as lower-risk populations not only have lower claims costs, but could result in potential accrued interest for their premium revenues, whereas issuers with higher-risk populations are expected to incur higher claims costs and would generally not be able to collect the potential accrued interest for their premium revenues. To further illustrate this issue, in a hypothetical State market risk pool with only two issuers, where the risk adjustment issuer with lower-risk enrollees owes a $1,000,000 charge and the risk adjustment issuer with higher-risk enrollees receives a payment of $1,000,000, the charge issuer may have accrued an additional $45,000 in interest from the initial $1,000,000, and after paying the risk adjustment charge, would retain the $45,000, while the payment issuer is deprived of the same opportunity. Thus, we have received feedback from interested parties expressing concern about this scenario in the context of the HHS-operated risk adjustment program and concerns about how it could create incentives for adverse selection that could result in issuers that receive State transfer payments raising premiums to recoup lost opportunity costs from the time value of money.

For these reasons, we solicit comments on the impact of the time value of money on the HHS-operated risk adjustment program, including the impact of the time value of money on issuers' assessment of actuarial risk and the incentives for adverse selection, and what possible solutions or mitigating steps we should consider to address the impact of the time value of money on the HHS-operated risk adjustment program in future rulemaking.

5. HHS Risk Adjustment User Fee for the 2026 Benefit Year (§ 153.610(f))

We propose an HHS risk adjustment user fee for the 2026 benefit year of $0.18 PMPM. Under § 153.310, 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 2026 benefit year, HHS will operate risk adjustment in every State and the District of Columbia. As described in the 2014 Payment Notice (78 FR 15416 through 15417), HHS' operation of the risk adjustment program on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a State, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–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.[84] The HHS-operated risk adjustment program provides special benefits as defined in section 6(a)(1)(B) of OMB Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associate with potential adverse risk selection.[85] The HHS-operated risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2025 Payment Notice (89 FR 26218), we calculated the Federal administrative expenses of operating the HHS risk adjustment program for the 2025 benefit year to result in a risk adjustment user fee rate of $0.18 PMPM based on our estimated costs for HHS risk adjustment operations and estimated billable member months (BMM) for individuals enrolled in risk adjustment covered plans. For the 2026 benefit year, HHS proposes to use the same methodology to estimate our administrative expenses to operate the program. These costs cover development of the models and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, interested parties training, operational support, and administrative and personnel costs dedicated to HHS-operated risk adjustment program activities. To calculate the risk adjustment user fee, we divided HHS' projected total costs for administering the program on behalf of States by the expected number of BMM in risk adjustment covered plans in States where the HHS-operated risk adjustment program will apply in the 2026 benefit year.[86]

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for the 2026 benefit year will be approximately $65 million, roughly the same as the amount estimated for the 2025 benefit year.

Similar to prior benefit years, we projected risk adjustment enrollment scenarios for the 2026 benefit year. For the 2021 through 2025 benefit years, we projected increased enrollment in the

[82] Section 1321(c)(1) of the ACA directs the HHS Secretary to operate the risk adjustment program in any State that fails to elect to do so. Since the 2017 benefit year, HHS has operated the program in all 50 States and the District of Columbia.

[83] The IRS publishes all annual short-term AFRs at: *https://www.irs.gov/applicable-federal-rates. January 2016 AFR: https://www.irs.gov/pub/irs-drop/rr-16-01.pdf; January 2023 AFR: https://www.irs.gov/pub/irs-drop/rr-23-01.pdf.*

[84] See Circular No. A–25 Revised. *https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.*

[85] Ibid.

[86] HHS did not receive any requests from States to operate risk adjustment for the 2026 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2026 benefit year.

individual non-catastrophic market risk pool in most States, due to the enhanced PTC subsidies provided for in the American Rescue Plan Act of 2021 (ARP) [87] [88] and the extension of the enhanced PTC subsidies under Section 12001 of the Inflation Reduction Act of 2022 (IRA) through the 2025 benefit year.[89] For our 2026 user fee projected enrollment numbers, we considered the impact of the expiration of the enhanced PTC subsidies established in section 9661 of the ARP and extended in section 12001 of the IRA through the 2025 benefit year on the enrollment in the individual, small group, and merged market risk pools for the 2026 benefit year and used those estimates to project the proposed 2026 benefit year HHS risk adjustment user fee rate. We also note that if any events such as Congress passing an extension of enhanced PTC subsidies, resulting in larger than expected growth in individual on Exchange enrollment or some other deviation from our expectations of current conditions that would significantly change our estimates around costs, enrollment projections, or the finalization of proposed risk adjustment policies between this proposed rule and the final rule, we may modify the HHS risk adjustment user fee rate proposed in this rule in the final rule. Because we project a similar budget to operate the HHS-operated risk adjustment program and do not estimate increased enrollment in the 2026 benefit year beyond the 2024 benefit year level, we propose an HHS risk adjustment user fee of $0.18 PMPM for the 2026 benefit year.

We seek comment on the proposed HHS risk adjustment user fee for the 2026 benefit year.

6. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§§ 153.350 and 153.630)

HHS conducts risk adjustment data validation under §§ 153.350 and 153.630 in any State where HHS is responsible for operating the risk adjustment program.[90] The purpose of risk adjustment data validation is to ensure issuers are providing accurate high-quality information to HHS, which is crucial for the proper functioning of the HHS-operated risk adjustment program. HHS–RADV also ensures that risk adjustment transfers calculated under the State payment transfer formula reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor quality data, thereby helping to ensure that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. HHS–RADV consists of an initial validation audit (IVA) and a second validation audit (SVA). Under § 153.630, each issuer of a risk adjustment covered plan must engage an IVA entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its IVA entity for data validation. Each issuer's IVA is followed by an SVA, which is conducted by an entity HHS retains to verify the accuracy of the findings of the IVA. Based on the findings from the IVA, or SVA (as applicable), HHS conducts error estimation to calculate an HHS–RADV error rate. The HHS–RADV error rate is then applied to adjust the plan liability risk scores of outlier issuers, as well as the risk adjustment transfers calculated under the State payment transfer formula for the applicable State market risk pools, for the benefit year being audited.

a. Initial Validation Audit (IVA) Sampling Methodology—Enrollees Without HCCs, Finite Population Correction, and Neyman Allocation (§ 153.630(b))

To better align the IVA sampling methodology with the HHS–RADV error estimation methodology that estimates hierarchical condition categories (HCC) error rates and to improve overall sampling precision, we are proposing to exclude enrollees without HCCs [91] from IVA sampling, to remove the Finite Population Correction (FPC), and to replace the source of the Neyman allocation [92] data used for IVA sampling purposes with 3 years of available HHS–RADV data beginning with benefit year 2025 HHS–RADV.[93]

1. IVA Sampling Background

HHS–RADV IVA sampling policy was originally described in the 2014 Payment Notice (78 FR 15436) where we stated that HHS would choose a sample size of enrollees for HHS–RADV such that the estimated risk score errors would be statistically sound, and the enrollee-level risk score distributions would reflect enrollee characteristics for each issuer. To implement this approach, in the 2015 Payment Notice (79 FR 13756 through 13758), we finalized two key aspects of the IVA sampling methodology. First, HHS set the IVA sample size as 200 enrollees per issuer, as sample size precision analyses performed at the time with data available from Medicare Advantage RADV (MA–RADV) program, which utilizes a similar HCC-based methodology as the HHS–RADV methodology, indicated that a sample size of 200 enrollees would achieve the targeted precision for an average sized issuer and that there would be no meaningful improvement in the estimated level of precision with larger sample sizes. In particular, to establish this 200-enrollee sample, we set a 10 percent sampling precision target at a two-sided 95 percent confidence level. That is, we aimed to obtain a sample size such that 1.96 multiplied by the standard error, divided by the estimated adjusted risk score, equals 10 percent or less.[94] [95] To translate this policy to small issuers, we established an FPC factor to calculate a modified IVA sample size smaller than 200 enrollees.[96] If an issuer

[87] ARP. Public Law 117–2 (2021).

[88] CMS. (2023). *Summary Report on Permanent Risk Adjustment Transfers for the 2022 Benefit Year.* (p. 8). *https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf.*

[89] Inflation Reduction Act. Public Law 1217–169 (2022).

[90] Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 States and the District of Columbia.

[91] Adult enrollees with only RXCs do not have any HCCs, and therefore, as further explained in this preamble, would be excluded from IVA sampling under this proposal.

[92] Neyman allocation is a method to allocate samples to strata based on the strata variances. A Neyman allocation scheme provides the most precision for estimating a population mean given a fixed total sample size. See *http://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n324.xml.*

[93] Activities related to the 2025 benefit year of HHS–RADV will generally begin in Spring 2026, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2025 benefit year. Changes to the IVA sampling methodology need to be finalized before HHS–RADV activities begin; therefore, we are proposing these IVA sampling changes begin with 2025 benefit year HHS–RADV due to the timing of this rulemaking. For an example of the typical annual HHS–RADV timeline, see the *2023 Benefit Year HHS–RADV Activities Timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.*

[94] See 79 FR 13756 through 13758. Also see CMS. (2013). *Affordable Care Act (ACA) HHS-Operated Risk Adjustment Data Validation (RADV) Process White Paper.* (pp. 26–28). *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_050718.pdf.*

[95] We established this sampling precision target in the initial year of HHS–RADV based on a survey of guidance from the OMB, Internal Revenue Service (IRS), and the HHS-developed Payment Error Rate Measurement (PERM) program.

[96] An FPC is traditionally used when sampling without replacement from a finite population and the sample size, n, is significant in comparison with

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has between 51 and 3,999 enrollees, the issuer's IVA sample size is calculated by multiplying the FPC factor, which is a factor less than one, by the standard sample size of 200.[97] If an issuer has 50 or fewer enrollees, its sample size is equal to its enrollment. Second, the policies finalized in the 2015 Payment Notice established that the IVA sampling methodology would use a simple age and risk score stratification that categorizes the relevant population into 10 strata, representing different demographic and risk score bands, and use a Neyman allocation sampling methodology to select an issuer's IVA sample for a given benefit year.[98] [99] [100] This stratified design was intended to ensure adequate sample selection of the higher risk portion of the enrollee population and the Neyman allocation increases the likelihood that the sample achieves targeted levels of precision because strata with greater variance will be sampled more heavily.[101]

Under the current risk score stratification in IVA sampling, to align with the HHS-operated risk adjustment program's three separate models for adult, child, and infants, we group each issuer's enrollee population into 10 strata based on age group, risk level, and presence of HCCs and prescription drug factors (RXCs) [102] as follows:

- Strata 1–3 includes low, medium, and high risk adults with the presence of at least one HCC or RXC.
- Strata 4–6 includes low, medium, and high risk children with the presence of at least one HCC.
- Strata 7–9 includes low, medium, and high risk infants with the presence of at least one HCC.
- Stratum 10 includes the No-HCC and No-RXC population, which is not further stratified by age group, because we assume this stratum has a uniformly low risk level.

The current IVA sampling methodology relies on MA–RADV proxy data to conduct the Neyman allocation, which optimizes stratum sample size by selecting the number of enrollees to be sampled from each of the 10 strata, listed above, that is proportional to each stratum's contribution to the total standard deviation of the population.[103] The Neyman allocation formula for the overall sample size for each stratum of the issuer's IVA sample ($n_{i,h}$) is:

$$n_{i,h} = n_i * \frac{N_{i,h}S_{i,h}}{\sum_{h=1}^{H} N_{i,h}S_{i,h}}$$

Where:

- $N_{i,h}$ is the population size of the h[th] stratum of issuer i.
- n_i is the IVA sample size of issuer i.
- H is the total number of strata.
- $S_{i,h}$ represents the standard deviation of risk score error amount for the h[th] stratum.

As described in the 2015 Payment Notice (79 FR 13756 through 13758), we use MA–RADV data to calculate the standard deviation of risk score error ($S_{i,h}$) across all 10 strata. At the time, we chose to use MA–RADV data when establishing the Neyman allocation because HHS–RADV data was not available and the MA–RADV program utilizes a similar HCC-based methodology. Because MA–RADV data does not have child or infant age groups, we can only calculate a single standard deviation of risk score error for each risk-score subgrouping (low, medium and high). Therefore, to use the MA–RADV data, we assume that the standard deviation of risk score error within a risk-score subgrouping is the same for each of the three age groups (adult, child, and infant) in the HHS–RADV population. Given our assumptions on the strata net risk score errors and variances from the MA–RADV data, we found that 200 enrollees would be an appropriate IVA sample size to achieve 10 percent sampling precision for net risk score error for an average-sized issuer. We also explained that we intended to test and evaluate HHS–RADV data for use for this purpose in future years when it became available.[104]

HHS–RADV error estimation has been modified over time without making corresponding changes to the IVA sampling methodology. For example, in the 2019 Payment Notice (83 FR 16961 through 16965), we finalized an HCC-failure rate error estimation methodology that adjusts an issuer's enrollees' risk scores when the issuer's failure rate for a group of HCCs is statistically different from a national benchmark.[105] This methodology specifically calculates IVA-sampled enrollees' risk scores using their HCCs on EDGE and adjusts the HCC-portion of enrollees' risk scores based on audit results for issuers identified as outliers.[106] In the 2020 Payment Notice, we finalized a policy to incorporate RXCs beginning with 2018 benefit year HHS–RADV, and the 2021 Payment Notice finalized treating RXC validations in HHS–RADV as late-filed discrepancies, similar to demographic and enrollment errors.[107] [108] [109] In

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the population size, N, so that no more than 5 percent of the population is sampled. The FPC formula can be found in Section 2.6: Cochran, William G., Sampling Techniques, third edition, John Wiley & Sons, 1977.

[97] See the *2023 Benefit Year PPACA HHS–RADV Protocols.* Section 7.2.1.8 (Alternate Sample Sizes) (June 4, 2024) available at: *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[98] See 79 FR 13756 through 13758.

[99] See supra note 92.

[100] In the initial years of HHS–RADV, we constrained the ''10th stratum'' of the IVA sample—that is, enrollees without HCCs selected for the IVA sample—to be one-third of the sampled IVA enrollees. In the 2020 Payment Notice, we finalized the extension of the Neyman allocation sampling methodology to the 10th stratum to improve sample precision and permit for a larger portion of the sample to be allocated to the HCC strata. *See* 84 FR 17494 through 17495.

[101] *See* 78 FR 72332.

[102] In the 2020 Payment Notice, we finalized piloting the incorporation of RXCs into the HHS–RADV process in the 2018 benefit year, which was the first year that RXCs were incorporated into the risk adjustment models. We also finalized incorporating RXC validation into HHS–RADV as a method of discovering materially incorrect EDGE server data submissions in a manner similar to how we address demographic and enrollment errors discovered during HHS–RADV beginning with the 2019 benefit year. See 84 FR 17501. We later extended the pilot years of incorporating RXCs into HHS–RADV to the 2019 and 2020 benefit years of HHS–RADV to increase consistency between the operations of these benefit years' HHS–RADV and facilitate the combination of the HHS–RADV adjustments for these benefit years as we transitioned to a concurrent application of HHS–RADV results. See 85 FR 77002 through 77005.

[103] In the Neyman allocation, risk score error is measured as the actual difference between enrollee's audit risk scores and EDGE risk scores and does not reflect the error rate derived in HHS–RADV error estimation.

[104] See 79 FR 13757.

[105] Failure rates are calculated based on the rate at which the IVA Entity (or the SVA Entity if these results are being used) was able to validate an issuer's HCCs during the HHS–RADV audit. Previously, individual HCCs were the unit of analysis for calculating failure rates. The 2023 Payment Notice finalized that coefficient estimation groups would be de-duplicated beginning with 2021 benefit year HHS–RADV, thereby altering the unit of analysis of failure rates to be de-duplicated Super HCCs, rather than individual HCCs. See 2023 Payment Notice, 87 FR 27208 at 27253–27256.

[106] See the HHS Notice of Benefit and Payment Parameters for 2019; Final Rule, 83 FR 16930 at 16961–16965 (April 17, 2018). Also see CMS. (2022, January 20). *Reissuing 2018 Benefit Year HHS Risk Adjustment Data Validation (RADV) Results Memo. https://www.cms.gov/files/document/reissuing-2018-hhs-radv-results.pdf.*

[107] See CMS. (2023). *Summary Report on Permanent Risk Adjustment Transfers for the 2022 Benefit Year.* (p. 8). *https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf.*

[108] As finalized in the 2020 Payment Notice, HHS does not use demographic and enrollment or RXC errors identified in HHS–RADV in its error rate calculations. Demographic and enrollment or RXC errors discovered during HHS–RADV are handled as late-filed discrepancies and may result in adjustments to the applicable benefit year RA transfer amount. See 84 FR 84 FR 17498 through 17503. Also see for example, Section 10.4 Validation of the 2023 Benefit Year PPACA HHS–RADV Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[109] Only adult enrollees can have RXCs and the frequency of RXCs among adult enrollees is relatively low. HHS currently uses the enrollees with RXCs in the IVA sample for validating RXCs

addition, in the 2024 Payment Notice, to promote consistency between the EDGE Server Business Rules and the HHS–RADV Protocols, HHS discontinued the Lifelong Permanent Conditions List and the policy permitting the submission of non-EDGE claims in HHS–RADV beginning with the 2022 benefit year of HHS–RADV.[110]

After running the HHS–RADV program for several years, we now have several years of HHS–RADV data that could be evaluated and used to improve our IVA sampling methodology. When we finalized the IVA sampling methodology, we stated that we would reexamine our sampling assumptions and methodology over time using actual HHS–RADV enrollee data as it becomes available. As a result of these analyses and for the reasons explained in the sections below, we are proposing changes to the IVA sampling methodology.

2. Proposal To Exclude Enrollees Without HCCs From IVA Sampling

We first propose to modify IVA sampling to exclude stratum 10 enrollees, which would exclude enrollees that do not have HCCs nor RXCs and adult enrollees in strata 1 through 3 that have RXCs only, from IVA sampling beginning with benefit year 2025 HHS–RADV. The purpose of this proposal to remove these enrollees (''enrollees without HCCs'') is to better align our IVA sampling methodology with the error estimation methodology that was established in the 2019 Payment Notice, which calculates issuer risk score error rates and applies these error rates to the HCC-related portion of issuers' plan liability risk scores,[111] and the HHS–RADV policies finalized in the 2024 Payment Notice to discontinue the Lifelong Permanent Conditions (LLPC) list and no longer allow non-EDGE claims beginning with the 2022 benefit year of HHS–RADV, which emphasize HHS–RADV's focus on validating enrollee HCCs on EDGE.[112] After the finalization of these policies, to validate an HCC in HHS–RADV, a risk adjustment eligible diagnosis must be supported by appropriate medical record documentation and linked to a risk adjustment eligible claim accepted by the issuer's EDGE server. IVA and SVA entities can no longer rely on the LLPC list or non-EDGE claims to support abstracting diagnoses that are not linked to an accepted risk adjustment eligible claim on the issuer's EDGE server. Under the current IVA sampling methodology, enrollees without HCCs are grouped into stratum 10 if they have no HCCs or RXCs, or into strata 1, 2, or 3 if they are adult enrollees with RXCs only (''RXC-only enrollees''). However, these enrollees do not have EDGE HCCs to validate during HHS–RADV. Moreover, they have HCC-associated EDGE risk scores equal to zero, so there is no risk score to adjust as a result of HHS–RADV. Therefore, this proposed policy to exclude enrollees without HCCs from IVA sampling ensures that issuers, IVA Entities, and SVA Entities (as applicable) are focusing resources on enrollees who have a more direct impact on Super HCC failure rates,[113] issuers' group failure rates, and issuers' error rates in HHS–RADV.

Furthermore, RXC-only enrollees have been included in the HHS–RADV sampling of strata 1 through 3 to ensure an adequate number of enrollees with RXCs in issuers' samples to complete HHS–RADV RXC validation.[114] However, EDGE data from benefit years 2019 through 2022 shows that on average less than 12 percent of an issuer's adult enrollee population with RXCs has no HCCs. Therefore, the vast majority of adult enrollees with RXCs also have HCCs and will therefore still be captured in strata 1 through 3 in the IVA sample and eligible for inclusion in the HHS–RADV RXC validation.[115] In addition, removing RXC-only enrollees from IVA sampling aligns our IVA sampling methodology with the HHS–RADV error estimation methodology, which does not consider RXCs in error estimation. We anticipate that this change will improve the precision of issuers' group failure rates for any given sample size by ensuring that all enrollees from stratum 1, 2 or 3 have EDGE HCCs to validate in HHS–RADV that contribute to issuers' error rate calculation. For these reasons, we propose to remove all enrollees without HCCs, which consists of stratum 10 enrollees and RXC-only enrollees, from IVA sampling. Under the proposal, enrollees without HCCs would be excluded from IVA sampling such that all 200 enrollees selected for IVA audit would have at least one EDGE HCC and would fall within strata 1 through 9.

3. Proposal To Remove the Finite Population Correction (FPC)

We propose to remove the FPC from the IVA sampling methodology such that, with the exclusion of enrollees without HCCs from IVA sampling, all issuers with at least 200 enrollees with HCCs in their enrollee population would have an IVA sample size of 200. Under this proposal, all issuers with fewer than 200 enrollees with HCCs would have an IVA sample size equal to their population of enrollees with HCCs. As previously explained, under the current IVA sampling methodology, issuers with between 51 and 3,999 enrollees in their total enrollee population are subject to the FPC and we calculate modified IVA sample sizes that are less than 200 enrollees using an FPC factor. Under the current approach, issuers with 50 or fewer enrollees have IVA sample sizes equal to their total enrollee population. We have found in recent years of HHS–RADV results that issuers with IVA sample sizes less than 200 enrollees are less likely to meet the 30 Super HCC constraint for outlier identification in a failure rate group.[116] If an issuer fails to meet the 30 Super HCC constraint in all three failure rate groups, the issuer cannot be determined to be an outlier and then the risk scores of their sampled enrollees are not

in HHS–RADVs. See Section 7.2.1.9 RXC Sample Size of the 2023 Benefit Year PPACA HHS–RADV Protocols.

[110] See 88 FR 25790 through 25796.

[111] See 83 FR 16930 at 16961 through 16965. Also see CMS. (2022, January 20). Reissuing 2018 Benefit Year HHS Risk Adjustment Data Validation (RADV) Results Memo. *https://www.cms.gov/files/document/reissuing-2018-hhs-radv-results.pdf.*

[112] For more detail on the 2024 Payment Notice policies regarding the LLPC list and non-EDGE claims, see 88 FR 25790 through 25796.

[113] As previously mentioned, the 2023 Payment Notice altered the unit of analysis of failure rates to be de-duplicated Super HCCs, rather than individual HCCs. See 87 FR 27208 at 27253—27256. For more detail on how Super HCC failure rates are calculated, see Section 13.3.1.1.3 Calculate Super HCC Failure Rates and Categorize Super HCCs into Low, Medium, and High Failure Rate Groups of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[114] As explained earlier in this preamble, HHS–RADV RXC validations are treated as late-filed discrepancies similar to demographic and enrollment errors. See 84 FR 17498 through 17503.

[115] IVA Entities validate RXCs by reviewing claims, not medical records. See Section 10.4 Validation of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[116] Under the outlier identification policy finalized in the 2021 Payment Notice, when HCCs were the unit of analysis of failure rates, an issuer could not be identified as an outlier in any failure rate group in which that issuer had fewer than 30 Super HCCs. See 85 FR 29196 through 29198. In the 2023 Payment Notice, when the unit of analysis of failure rates was altered to de-duplicated Super HCCs, we finalized the policy to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 de-duplicated EDGE Super HCCs. Issuers with fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group may still be considered an outlier in other failure rate groups in which they have 30 or more de-duplicated EDGE Super HCCs. See 87 FR 27254.

adjusted during error estimation.[117] However, in our analysis of the proposal to exclude enrollees without HCCs from IVA sampling, we found that removing the FPC would give smaller issuers a better opportunity to increase the count of Super HCCs in their IVA sample because all enrollees sampled would have at least one HCC. Alternatively, retaining the FPC would continue to adjust these issuers' sample sizes downwards and greatly limit the number of Super HCCs in their IVA samples. By including more enrollees with HCCs in these smaller issuers' IVA samples, we would increase these issuers' probability of meeting the 30 Super HCC constraint and improve the precision of group failure rates during error estimation, as well as improve the precision of net risk score error as discussed below. In addition, for small issuers that meet the 30 Super HCC threshold, this proposal would further allow these issuers' risk scores to be appropriately adjusted if they are identified as outliers, and it would allow them to gain additional insights from a richer set of data elements reported in their HHS–RADV results to improve coding practices and EDGE data submission procedures (as applicable). For these reasons, we are proposing to remove the FPC beginning with 2025 benefit year HHS–RADV.

Under this proposal, issuers with less than 200 enrollees with HCCs would have all enrollees with HCCs in their IVA sample. The issuer-specific sample size would be equal to the sum of all of their enrollees with HCCs in strata 1 through 9 in their EDGE population subject to HHS–RADV.[118] For issuers with at least 200 enrollees with HCCs, their IVA sample size would remain at 200 enrollees and HHS would continue to use the Neyman allocation to determine stratum sample sizes for enrollees with HCCs in strata 1 through 9.[119]

Based on an analysis of historical HHS–RADV data, we estimate that issuers with less than 1,200 enrollees or approximately 10,000 billable member months statewide would be likely to have insufficient enrollees with HCCs in strata 1 through 9 to create an IVA sample size with 200 enrollees. These issuers would therefore have an IVA sample size equal to their EDGE population of enrollees who have HCCs. In the absence of the FPC, small issuers may have IVA sample sizes that are larger or smaller than their IVA sample size would have been if subjected to the FPC under the current methodology. However, any increase in IVA sample size would only be realized in the years that a smaller issuer is selected for HHS–RADV, which is approximately once every 3 years (barring any risk-based triggers that would warrant more frequent audits) under the materiality threshold exemption at § 153.630(g)(2).[120] In addition, we anticipate that the smaller issuers whose sample sizes would increase if the proposal to remove the FPC is finalized would also have an increase in Super HCC count in their IVA samples and group failure rate precision.[121] As the set of data used to estimate an issuer's group failure rates increases, the precision of those sample estimates also increases, which is important as the issuer's outlier status depends on whether their group failure rates fall within the national benchmark confidence intervals. More specifically, we estimate that issuers receiving the FPC under the current methodology and whose IVA sample sizes would increase under the proposed methodology would see a 35 percent increase in Super HCC count in their IVA samples and a 26 percent increase in group failure rate precision on average across all three failure rate groups.[122] We discuss the aggregate impact of all proposed IVA sampling policies, including the proposed removal of the FPC, on issuer burden in section 5 of this preamble and in the ICR section of this rule.

4. Proposal To Source the IVA Sampling Neyman Allocation With HHS–RADV Data

We also propose to change the current IVA sampling methodology to replace the source of the Neyman allocation data with HHS–RADV data now that we have accumulated sufficient HHS–RADV data to test and evaluate using it for IVA sampling purposes. As explained earlier in this preamble, relying on the MA–RADV in the Neyman allocation requires a simplifying assumption that the standard deviation of risk score error within a risk-score subgrouping (low, medium, and high) is the same for the three age groups (adult, child, and infant). However, we have found that the variance of net risk score error differs considerably, both between the MA–RADV data and the available HHS–RADV data and across strata. Because the Neyman allocation calculates the optimal allocation to each stratum such that strata with greater variance in net risk score error are sampled more intensely and strata with less variance in net risk score error are sampled less intensely, this implies that the MA–RADV data yields considerably different sample sizes for each stratum than the HHS–RADV data. For example, our analysis found that while the median sample proportion of stratum 3 (Adult—High risk) enrollees is 39 percent using the MA–RADV data, this could decrease to 19 percent of the sample being composed of stratum 3 enrollees if HHS–RADV data were used.[123]

For these reasons, beginning with 2025 benefit year HHS–RADV, we are proposing to no longer use MA–RADV data to calculate the standard deviation of risk score error ($S_{i,h}$) for use in the Neyman allocation and instead use a 3-year rolling-window of available HHS–RADV data. For a given benefit year of HHS–RADV, we would use the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin as the source data for the Neyman allocation and would continue to combine enrollees in each stratum across all issuers to create a national variance of net risk score error to calculate the standard deviation of risk score error ($S_{i,h}$).[124] [125] We considered

[117] An issuer cannot be considered an outlier for a failure rate group in which the issuer has fewer than 30 de-duplicated EDGE Super HCCs but data from these issuers' failure rates is included in the calculation of national benchmarks. See 87 FR 27254 through 27255.

[118] An issuer's EDGE population only consists of enrollees in their risk adjustment covered plans. See §§ 153.610(a) and 153.700(a). However, for example, issuers that are the sole issuer in a State market risk pool are not subject to risk adjustment data validation and therefore a sole issuer risk pool's enrollment would not be included in the population subject to HHS–RADV sampling. See 83 FR 16967.

[119] If the Neyman-allocated sample size for a stratum exceeds the number of enrollees in that stratum, HHS uses the actual number of enrollees in that stratum in the issuer's population in place of the target Neyman-allocated sample size for that stratum. The Neyman optimal allocation method is then performed again using a positive or negative incremental value to adjust the target sample size, until the actual sample size derived by summing the Neyman output for strata 1 through 9 meets the target IVA sample size of 200.

[120] Issuers at or below the materiality threshold of 30,000 billable member months are only subject to random and targeted sampling every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audit), and issuers below 500 billable member months statewide are exempt from HHS–RADV. See 88 FR 25788 through 25790.

[121] As explained in section 5 of this preamble, this estimate is based on the combination of all proposed changes to the IVA sampling methodology.

[122] Ibid.

[123] As noted later in this preamble, this estimate reflects the combined impact of all proposed changes to the IVA sampling methodology.

[124] A new benefit year of HHS–RADV activities generally begins in the spring the year following the applicable benefit year when issuers can start selecting their IVA entity and IVA entities can start electing to participate in HHS–RADV for that benefit year. See, for example, the 2023 Benefit Year HHS–RADV Activities Timeline for the general

creating an issuer-specific variance of net risk score error given the proposed shift to using HHS–RADV data instead of MA–RADV data for IVA sampling purposes, but this would not be possible for all issuers as some issuers would not have 3 consecutive years of HHS–RADV data. For example, consistent with § 153.630(g)(2), an issuer that is at or below the materiality threshold for random and targeted sampling will only be sampled for HHS–RADV approximately once every 3 years and therefore would not have HHS–RADV data for the years that they are not sampled. These issuers would have to rely on fewer years of HHS–RADV data, meaning significantly fewer data points compared to other issuers that participated in all years, which could result in large variations in IVA sample stratum size and increased uncertainty in HHS–RADV. Therefore, we propose to continue calculating $S_{i,h}$ with a national variance of net risk score error, but to use a 3-year rolling window of HHS–RADV data rather than the MA–RADV data as the source data for the Neyman allocation. Under this proposed approach, we would re-calculate $S_{i,h}$ during each benefit year of HHS–RADV to use the 3 most recent consecutive years of HHS–RADV data with results that have been released before each benefit year's HHS–RADV activities begin. This proposed approach is consistent with our shift from the use of MarketScan® data to recalibrate the HHS risk adjustment models to instead use the 3 most recent consecutive years of enrollee-level EDGE data that are available at the time we incorporate the data in the draft recalibrated risk adjustment model coefficients published in the proposed rule for the applicable benefit year. In the context of HHS–RADV, a 3-year rolling window would capture population changes that occur over time while promoting stability in the estimates of $S_{i,h}$ in HHS–RADV year over year. For example, annual improvements in issuers' EDGE data submission could decrease differences between enrollees' HHS–RADV audit risk scores and EDGE risk scores, while annual changes in enrollment and EDGE enrollee risk profiles could change the enrollee stratification, such that the standard deviation of risk score error for each stratum changes over time. In addition, under our random and targeted sampling policy for HHS–RADV, issuers below the materiality threshold participate in HHS–RADV approximately once every 3 years. Therefore, using a 3-year rolling window will help ensure the majority of issuers participating in HHS–RADV are reflected in the strata metrics.

In addition, the proposal to use HHS–RADV data rather than the MA–RADV data as the source data for the Neyman allocation would decrease burden on issuers and IVA Entities. More specifically, our analysis found that the MA–RADV data yields considerably different sample sizes for each stratum than the HHS–RADV data, and that using the HHS–RADV data rather than the MA–RADV data is likely to increase the proportion of the sample in the lower-risk groups and decrease the proportion of the sample in the high-risk group. This proposed change in sampled enrollees means that under this proposal, issuers would have relatively fewer medical records to review because of the increase in the proportion of sampled enrollees in the lower-risk strata and the decrease in the proportion of enrollees in higher-risk strata. To further explain, this decrease in estimated medical record review would occur because higher-risk enrollees tend to have relatively more medical records to review than lower-risk enrollees. Issuers spend time and resources on retrieving, reviewing, and submitting medical records and documentation for HHS–RADV, so the estimated decrease in the average number of medical records reviewed per enrollee in the IVA sample from replacing MA–RADV data with HHS–RADV data is expected to lead to a decrease in issuer burden. We further address the estimated aggregate burden impact of all IVA sampling policies proposed in this rule in section 5 of this preamble and the ICR section of this rule.

5. Impact of IVA Sampling Proposals

In preparation for proposing changes to HHS–RADV IVA sampling, HHS conducted several analyses to evaluate the impact of these proposals. Our analysis revealed that the proposed modifications to switch data for the Neyman allocation to use the 3 most recent consecutive years of HHS–RADV data with results that have been released before HHS–RADV activities begin for the given benefit year, combined with the proposal to remove enrollees without HCCs from IVA sampling, and to remove the FPC would improve our ability to reach the 10 percent sampling precision target for net risk score error for a greater proportion of issuers in HHS–RADV.[126] More specifically, when we evaluated the proposed IVA sampling methodology reflecting the changes outlined in this rule, which excludes enrollees without HCCs, removes the FPC, and replaces the MA–RADV data with available HHS–RADV data as the source data for the Neyman allocation, using HHS–RADV data from the 2022 benefit year, we found that more than 99 percent of issuers met the 10 percent sampling precision target for net risk score error at a two-sided 95 percent confidence level.

Our analysis also focused on the impact of the proposed policies on group failure rate precision. Previously, in the 2019 HHS–RADV White Paper, we evaluated how precise the current IVA sampling methodology was in measuring group failure rates and estimated that approximately 60 percent of issuers with a sample size of 200 enrollees met 10 percent group failure rate precision in all three HCC groups.[127] In comparison, under the proposed changes to the IVA sampling methodology in this rule, our analysis found that approximately 91 percent of all issuers in HHS–RADV would meet the 10 percent group failure rate precision in all three Super HCC groups. Moreover, approximately 87 percent of issuers with IVA sample sizes less than 200 would also meet the 10 percent group failure rate precision target in all three Super HCC groups.

In addition, we anticipate that the proposed changes to the IVA sampling methodology in this rule would result in an overall decrease in the number of medical records reviewed by IVA Entities. Issuers spend time and resources on retrieving, reviewing, and submitting medical records and documentation for IVA Entities to review, so the estimated decrease in medical records reviewed is expected to lead to a decrease in issuer burden. Although every enrollee sampled for the IVA would have HCCs, the proportion of enrollees sampled from strata 1 through 9 would change such that enrollees with more medical records are sampled less intensely due to the replacement of MA–RADV data with HHS–RADV data for the Neyman allocation. As mentioned earlier in this preamble, the median sample proportion of high-risk adult enrollees,

structure of the HHS–RADV timeline. *https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.*

[125] As an example, if finalized as proposed, we would use HHS–RADV data from benefit years 2021, 2022 and 2023 for the Neyman allocation for benefit year 2025 HHS–RADV.

[126] The precision of net risk score error reflects the ability of the IVA sampling methodology to consistently estimate the percent difference between enrollees' audit risk scores and EDGE risk scores. See Section 1. IVA Sampling Background of this preamble for more detail on how the 10 percent sampling target was derived.

[127] See Section 2.3.6 Precision of Current Sample Sizes of the 2019 HHS–RADV White Paper.

who have more medical records to review on average, could decrease from 39 percent of the sample to 19 percent under the updated IVA sampling methodology reflecting the proposed changes in this rule. We describe our estimates of the proposed methodology on issuer burden in more detail in the ICR section of this rule.

We also analyzed the impact of replacing the source data for the Neyman allocation with HHS–RADV data while continuing to include enrollees without HCCs in IVA sampling and retaining the FPC. However, this would result in sampling a greater proportion of enrollees without HCCs, who do not have risk scores to adjust when calculating issuers' error rates during HHS–RADV. In addition, keeping the FPC while excluding enrollees without HCCs from IVA sampling and replacing the source data for the Neyman allocation with available HHS–RADV data would lead to a dramatic increase in the number of issuers subject to the FPC and therefore decrease the total count of Super HCCs in issuers' IVA samples. For example, we estimate that the average Super HCC count for issuers currently subject to the FPC would decrease by 26 percent by keeping the FPC, which would increase the proportion of issuers that fail to meet the 30 Super HCC constraint in HHS–RADV. In contrast, removing the FPC would increase the average Super HCC count for these same issuers by 30 percent, which would improve these issuers' probability of meeting the 30 Super HCC constraint. Overall, we found that making all proposed modifications in unison led to the greatest improvements in sampling precision and group failure rate precision across all issuers and a decrease in aggregate issuer burden.

As explained above, removing enrollees without HCCs and the FPC, and updating the source of the IVA sampling Neyman allocation data to use HHS–RADV data, leads to an IVA sample that improves sampling precision while decreasing burden on issuers and IVA Entities on average. Therefore, we are proposing to exclude enrollees without HCCs from IVA sampling such that each enrollee in an issuer's IVA sample must have at least one HCC, remove the FPC, and discontinue use of MA–RADV data as the source for the Neyman allocation calculation and begin using the 3 most recent consecutive years of HHS–RADV data with results that have been released before HHS–RADV activities for the benefit year begin.

We solicit comments on these proposed changes to the IVA sampling methodology, the estimated impact of the changes, the timing of the implementation of the IVA sampling changes and feedback on whether there are other IVA sample changes that should be considered.

We seek comment on these proposals.

a. b. Second Validation Audit (SVA) Pairwise Means Test (§ 153.630(c))

To improve the sensitivity of the SVA pairwise means test, we propose to modify the test, which currently uses a paired sample t-test methodology, to use a bootstrapping methodology, and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.[128]

In the 2014 Payment Notice (78 FR 15437), we established that an SVA will be conducted by an entity retained by HHS to verify the accuracy of the findings of the IVA. Consistent with § 153.630(c), HHS selects a subsample of the risk adjustment data validated by the IVA for the SVA. The HHS–RADV SVA sampling methodology was originally developed in the 2015 Payment Notice (79 FR 13761) and is designed to identify statistical differences between the IVA and SVA results. To do this, the SVA Entity currently starts by reviewing the medical records of an initial subsample of 12 enrollees from the IVA sample. The SVA subsample expands to include 24, 50, and 100 enrollees in the IVA sample[129] when statistically significant differences between the IVA and SVA results are identified at the sample-level under review. The SVA Entity identifies statistically significant differences in subsampled enrollees' IVA and SVA results using a paired sample t-test, which currently uses the t-distribution to build a 95 percent confidence interval around the difference between enrollee's IVA and SVA risk scores. If this confidence interval includes zero, then a statistically significant difference is not detected, and the issuer's IVA results are used in error estimation. If this confidence interval does not include zero, then there is a pairwise means testing failure at that subsample level, which requires SVA expansion to the next subsample level. As finalized in the 2020 Payment Notice (84 FR 17498), if the issuer fails the pairwise means test at SVA 100, a precision analysis is performed to determine whether the SVA audit results from the SVA 100 subsample can be used in error estimation or if the SVA sample needs to expand to the full IVA sample of 200 enrollees[130] with the SVA 200 results used in error estimation.[131]

The pairwise means testing procedure promotes the integrity and effectiveness of HHS–RADV by ensuring that error estimation and the HHS–RADV adjustments to risk scores are based on the most reliable medical coder review data possible. As such, it is important that the pairwise means testing procedure can detect when issuers' IVA results significantly differ from their SVA results at the initial sample size. Based on our experience operating HHS–RADV for the past several benefit years, we have reassessed the sensitivity of our pairwise means testing procedure, meaning the ability of the statistical test to identify statistically significant differences between IVA and

[128] Activities related to the 2024 benefit year of HHS–RADV will generally begin in March 2025, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2024 benefit year. The SVA typically starts the January 2 years after the applicable benefit year (January 2026 for the 2024 benefit year of HHS–RADV) once issuers' IVA results have been submitted. See HHS. (2024, March 27). *2023 Benefit Year HHS–RADV Activities Timeline for the general structure of the HHS–RADV timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.* These changes to the SVA framework do not impact or change issuer or IVA Entity obligations or requirements; therefore, we are proposing to implement the proposed changes to the SVA pairwise means test starting with the 2024 benefit year HHS–RADV.

[129] A standard HHS–RADV IVA sample size is 200 enrollees, and it applies to the majority of issuers of risk adjustment covered plans. CMS calculates a smaller IVA sample sizes for issuers with smaller populations by using a Finite Population Correction (FPC) factor. All issuers are subject to the same SVA subsample sizes, but the maximum SVA subsample for pairwise testing is one half of the issuer's IVA sample size. As discussed in section II.B.5.a, we are proposing changes to the IVA sampling methodology that would exclude enrollees without HCCs from IVA sampling and remove the FPC factor such that all IVA samples will consist of 200 enrollees with HCCs or the issuer's total population of enrollees with HCCs if they have less than 200 enrollees with HCCs beginning with the 2025 benefit year of HHS–RADV. Under this policy, the SVA subsample size expansion for issuers with less than 200 enrollees with HCCs would continue to follow the standard SVA subsample sizes with a maximum SVA subsample for pairwise testing equal to one half of the issuer's IVA sample size. If the issuer fails at the maximum SVA subsample size for pairwise testing, a precision analysis is performed to determine whether the SVA audit results from that maximum SVA subsample size can be used in error estimation or if the SVA sample needs to expand to the full IVA sample.

[130] Id.

[131] See Section 11.6.2 Pairwise Means Test to Determine Accepted Results (IVA vs. SVA) of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.* For issuers with the FPC, if there is insufficient agreement between IVA and SVA findings at the maximum total SVA subsample for pairwise testing, a precision analysis is performed to determine whether it is necessary to expand the SVA sample to the full IVA sample for error estimation.

SVA risk scores when they exist, to see whether changes are needed. Based on our reassessment, we believe that the pairwise means testing procedure should be modified to use a 90 percent bootstrapped confidence interval, rather than a t-test with a 95 percent confidence interval, and to increase the initial SVA subsample level from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV to improve the detection of differences between IVA and SVA results.

To assess our current pairwise means testing procedure, we conducted a power analysis to investigate its sensitivity in detecting population-level differences. The analysis focused on ''false negatives,'' a detection error that occurs when there are significant differences between IVA and SVA results, but the statistical test does not identify a statistically significant difference between IVA and SVA enrollee risk scores. We are concerned about ''false negatives'' and therefore focused on them because they result in an atypical issuer passing the pairwise means test and the conclusion of the SVA review without further investigation at a higher subsample level. Our power analysis found that when using a subsample size of 12 enrollees the current paired sample t-test using a 95 percent confidence interval results in a false negative rate of over the target false negative rate of 20 percent at any of the simulated effect sizes.[132] [133]

As part of our examination of ways to address our concerns about false negatives in the current pairwise means testing procedure, we expanded our power analysis by investigating the use of a bootstrapping methodology as an alternative pairwise means testing procedure to identify statistically significant differences between IVA and SVA risk scores. A bootstrapping approach is a useful technique to construct confidence intervals when the underlying distribution is unknown, when sample size may be too small to assume a normal sampling distribution, or when no formula exists to describe the sampling distribution of a particular point estimate.[134] When conducting the SVA pairwise means test, we do not know each issuer's population distribution of IVA and SVA risk score differences because our sample is limited to the applicable SVA subsample level. However, by simulating bootstrapped samples based on observed IVA and SVA risk score differences at a given SVA subsample level, we can build each issuer's sampling distribution and calculate standard errors and confidence intervals to improve the sensitivity of the test used to identify statistically significant differences between IVA and SVA results.

In particular, at a given SVA subsample level, the proposed pairwise bootstrapping methodology would perform 10,000 iterations of resampling with replacement from the enrollees in the issuer's SVA subsample at that level. The average difference between enrollees' IVA and SVA risk scores would be calculated for each resample to build an issuer-specific confidence interval for statistical testing of enrollee's IVA and SVA risk scores. Like the current pairwise means test, if the bootstrapped confidence interval contains zero, the bootstrapping procedure would show non-significant differences between IVA and SVA risk scores, and the issuer would pass pairwise means testing at that SVA subsample level and IVA results would be used in error estimation. If the bootstrapped confidence interval does not include zero, the differences between IVA and SVA risk scores identified would be statistically significant, and the issuer would fail pairwise means testing at that SVA subsample level. In these circumstances, the SVA subsample would be expanded and the pairwise means test conducted at that new SVA subsample level. If the issuer continues to fail the pairwise means test at the SVA 100-level, a precision analysis would be performed to determine whether the SVA audit results from the SVA 100 subsample can be used in error estimation or if the SVA sample needs to expand to the full IVA sample of 200 enrollees with the SVA 200 results used in error estimation.[135]

We tested the bootstrapping methodology using a variety of confidence levels and found that using a bootstrapped confidence interval of 90 percent, rather than the current paired t-test with a 95 percent confidence interval, improves the pairwise means testing procedure's sensitivity and ability to detect when issuers' IVA results differ substantially from their SVA results. The proposed bootstrapping methodology with a 95 percent confidence interval achieves a lower rate of false negatives at smaller sample sizes for any given effect size compared to the current paired t-test methodology. Moreover, decreasing the size of the confidence interval from 95 percent to 90 percent under the bootstrapping methodology decreases the sample size required to achieve a targeted false negative rate of 20 percent, and therefore increases the probability of detecting significant differences when they exist. On the other hand, decreasing the confidence interval from 95 percent to 90 percent implies that the rate of false positives, or the rate at which an enrollee population with no major differences between IVA and SVA results would return a statistically significant finding at a given sample size, would increase from 5 percent to 10 percent. The reasonable increased false positive rate, in combination with the increased sensitivity of the bootstrapping methodology, would result in more issuers being expanded to larger SVA sample sizes during pairwise means testing. However, we believe that the increased false positive rate is necessary and appropriate to achieve an acceptable rate of false negatives and ensure that reliable audit results are used in error estimation. We also believe that in comparison to false negatives, false positives can be addressed through the expansion of the sample size and therefore, pose less of a concern than false negatives, which cannot be corrected for since a false negative would end the SVA review at the lower sample size. Therefore, we believe that the proposed changes to improve the sensitivity of the SVA pairwise means test achieve the right balance between false negatives and false positives.

Because the false negative rate decreases as sample size increases, the power analysis also showed the advantages of increasing the initial SVA subsample size beyond 12 enrollees. Specifically, under the proposed

[132] These effect sizes use the Cohen's D effect size measure and correspond to the recommended interpretations of a small, medium, and large effect size. See Cohen, Jacob (1988). Statistical Power Analysis for the Behavioral Sciences. Routledge. ISBN 978–1–134–74270–7. pp 25–27.

[133] The conventional minimum power desired for most research settings is 80 percent, which implies a false negative rate of 20 percent. See Cohen, Jacob (1988). *Statistical Power Analysis for the Behavioral Sciences.* Routledge. ISBN 978–1–134–74270–7. pp. 25–27.

[134] We use bootstrapping techniques in other parts of HHS–RADV error estimation, such as for calculating error rate precision. See Section 11.6.3 Calculating Error Rate Precision of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[135] See Section 11.6.2 Pairwise Means Test to Determine Accepted Results (IVA vs. SVA) of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

bootstrapping methodology using a 90 percent confidence interval, we could achieve a false negative rate of 20 percent at medium and large effect sizes by increasing the initial SVA subsample size to 24 enrollees. We also recognize these proposed changes to increase the initial review sample size and adopt the proposed bootstrapping methodology using a 90 percent confidence interval, would likely increase the scale of HHS' SVA review and therefore increase the costs to conduct the SVA. While the increase in the scale of HHS' SVA review would increase costs, as discussed in the regulatory alternatives section of this rule, we do not anticipate the proposed changes to improve the sensitivity of the SVA pairwise means test will significantly impact the timeline to conduct error estimation. As in any year of HHS–RADV, the timeline for conducting error estimation may be adjusted in response to the volume of SVA discrepancies submitted because the SVA discrepancy window occurs prior to the release of error rate results. Ultimately, we believe that these proposed changes to improve the sensitivity of the SVA pairwise means test are necessary and appropriate to address the identified concerns regarding ''false negatives'' and to promote the integrity of HHS–RADV. Therefore, we are proposing to modify the pairwise means test to use a bootstrapping methodology using a 90 percent confidence interval and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.

We seek comment on the proposal to modify the SVA pairwise means testing procedure to use a bootstrapped 90 percent confidence interval and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.

b. c. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

We propose to amend § 156.1220(a) to codify a new, second materiality threshold for HHS–RADV appeals, hereafter referred to as the materiality threshold for rerunning HHS–RADV results.[136] This proposal would codify a standard for when HHS would take action to rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal. We propose to amend § 156.1220 to add a new paragraph (a)(2)(i) to provide that HHS would rerun HHS–RADV results in response to an appeal when the impact to the issuer who submitted the appeal (that is, the filer's) HHS–RADV adjustments to State transfers is greater than or equal to $10,000. This proposal is further discussed in part 156 (§ 156.1220) below.

C. Part 155—Exchange Establishment Standards and Other Related Standards

1. Solicitation of Comments—Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§ 155.210, 155.215, and 155.225)

We are soliciting comment regarding how assisters who perform their assister duties in a hospital and hospital system may, within the bounds of the statute, refer consumers to programs designed to reduce medical debt.

Sections 1311(d)(4)(K) and 1311(i) of the ACA direct all Exchanges to establish a Navigator program. Navigator duties and requirements for all Exchanges are set forth in section 1311(i) of the ACA and § 155.210. Section 1321(a)(1) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, for, among other things, the establishment and operation of Exchanges. Pursuant to section 1321(a)(1) of the ACA, the Secretary issued § 155.205(d) and (e), which requires Exchanges to perform certain consumer service functions in addition to the Navigator program. To satisfy these requirements, Exchanges may establish a non-Navigator assistance personnel program, as the FFEs have done, and must have a Certified Application Counselor (CAC) program. Existing regulations outlining duties and required activities for Navigators (§ 155.210(e)), non-Navigator assistance personnel (§ 155.215, through the cross-reference to § 155.210(e)), and CACs (§ 155.225(c)) were initially finalized in the 2015 Market Standards final rule (79 FR 30240).

The purpose of these assister programs is to ensure there are various ways consumers can receive help as they apply for and enroll in coverage through the Exchanges. In particular, Navigators (among other duties) help consumers make informed decisions during the health coverage selection process in a fair and impartial way, provide assistance in culturally and linguistically appropriate ways,[137] and assist consumers with certain post-enrollment activities such as understanding the process of filing eligibility appeals as well as basic concepts and rights related to health coverage and how to use it. Non-Navigator assistance personnel conduct direct assister-to-consumer outreach alongside Navigators to provide consumers with information in a fair and impartial way, which includes providing assistance with submitting the eligibility application, clarifying distinctions among health coverage options and helping consumers make informed decisions during the health coverage selection process. CACs provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible, assist consumers with applying for coverage in a QHP, and help facilitate enrollment of eligible individuals in QHPs and insurance affordability programs.

The Consumer Financial Protection Bureau estimates that $88 billion of outstanding medical bills are currently in collections, affecting one in five Americans.[138] High levels of medical debt, and their impact on consumer credit scores, have led to cascading negative effects for consumers and their families such as reduced credit, greater risk of personal bankruptcy, delays in seeking necessary health care services, and housing insecurity. These challenges also disproportionately fall on more vulnerable or underserved consumers, including young adults, veterans, people with low incomes, and Black and Hispanic populations.[139] Assister programs located within hospitals or as part of hospital systems could help ensure that the consumers they serve are aware of the financial assistance programs those entities provide. This can ultimately help to ensure the financial well-being of consumers as they seek health care.

We are interested in receiving comments about what we may do within the scope of our authority as it

[136] For purposes of this proposal, rerunning HHS–RADV results involves recalculating all national program benchmarks and issuers' error rate results, reissuing issuers' error rate results, conducting discrepancy reporting and appeal windows for the reissued results, applying the reissued error rates to the applicable benefit year's State transfers, and invoicing, collecting, and distributing any additional changes to the HHS–RADV adjustments to State transfers.

[137] Navigators receiving federal financial assistance are required to comply with the Section 1557's requirements on access for individuals with limited English proficiency, see CFR 45 § 92.201: *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-92.*

[138] Consumer Financial Protection Bureau. (n.d.) *Medical Debt. https://www.consumerfinance.gov/rules-policy/medical-debt/.*

[139] See for example, Levey, N. (2022, June 16). *100 Million People in America Are Saddled With Health Care Debt—KFF Health News.* KFF Health News. *https://kffhealthnews.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/.*

relates to Navigators and other assisters to help connect consumers to financial assistance programs within hospitals, hospital systems, and their communities.

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

a. Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies

We address our authority under § 155.220 to reach misconduct or noncompliance occurring at an agency-level,[140] by undertaking compliance reviews of and enforcement action against an insurance agency's (''agency's'') ''lead agent(s),'' [141] and discuss how we intend to utilize this authority to hold agencies accountable for misconduct or noncompliance with applicable HHS Exchange standards and requirements under § 155.220.

Section 155.220 currently applies to an agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for APTC and CSRs for coverage offered through an Exchange. ''Web-broker'' is defined in § 155.20 as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221.[142] Section 155.20 defines ''agent or broker'' as a person or entity licensed by the State as an agent, broker or insurance producer.

We are not proposing amendments to our existing regulations to codify our approach to hold agencies accountable for misconduct or noncompliance with applicable standards and requirements in § 155.220 because they can reasonably be interpreted to apply to agencies that are involved in Exchange enrollment transactions, since agencies are entities licensed by the State as an agent, broker, or insurance producer. As such, agencies would fall under the current definitions of ''agent or broker'' and ''web-broker'' in § 155.20.

Many FFE or SBE–FP enrollments are conducted by individual agents, brokers, or web-brokers who work for an agency and provide the agency's business NPN on the consumer's eligibility application submitted to an FFE or SBE–FP. An agency's business NPN can be included on a consumer's eligibility application when individual agents, brokers, or web-brokers who work at the agency are assisting consumers with enrolling in QHPs or applying for APTC and CSRs and the person associated with the agency's business NPN completes the FFE registration process, takes the required training, and signs the applicable Exchange Agreements [143] with CMS. These are annual requirements that need to be met anew each plan year.[144] In addition, Exchange enrollees or applicants may provide their consent to enroll in a QHP offered through an Exchange to an entire agency instead of, or in addition to, an individual agent, broker, or web-broker. This provides more flexibility, both for agents, brokers, web-brokers, and enrollees and applicants, by helping ensure consumers are able to reach someone who is authorized to assist them if they have questions or wish to make a plan change in the future, which also helps improve the consumer's experience.

The listing of a business NPN on the consumer's eligibility application or enrollment transaction submitted to an FFE or SBE–FP underscores the importance of holding agencies accountable for complying with the same standards and requirements as individual agents, brokers, or web-brokers. Applications and enrollments submitted to an FFE or SBE–FP that include a business NPN can impact Exchange operations, Exchange information technology systems, and Exchange enrollees or applicants, similar to situations where an individual agent, broker, or web-broker who does not work for an agency submits an application or enrollment to an FFE or SBE–FP. As such, we are addressing our authority to reach misconduct or noncompliance occurring at an agency-level and discussing how we intend to utilize this existing authority to hold agencies accountable for agency-level misconduct or noncompliance.

Section 1312(e) of the ACA directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll individuals and employers in QHPs through an Exchange and to assist individuals in applying for financial assistance for QHPs sold through an Exchange. In addition, section 1313(a)(5)(A) of the ACA directs the Secretary to provide for the efficient and nondiscriminatory administration of Exchange activities and to implement any measure or procedure the Secretary determines is appropriate to reduce fraud and abuse. Section 1321(a) of the ACA provides broad authority to the Secretary to establish standards and issue regulations to implement the statutory requirements related to Exchanges, QHPs, and other components of title I of the ACA, which includes sections 1312 and 1313 of the ACA, and this statutory provision also provides the Secretary authority to implement other requirements as the Secretary determines appropriate. In prior rulemakings, we used these authorities to adopt § 155.220, which establishes standards and requirements applicable to agents, brokers, and web-brokers assisting individuals, employers, or employees with enrollment in QHPs offered through an Exchange.

We propose to utilize the same authorities against lead agents [145] that are currently used to engage in compliance reviews of and enforcement actions against agents, brokers, and web-brokers. This includes the agent, broker, and web-broker compliance reviews and enforcement actions under § 155.220, which allow HHS to periodically monitor and audit an agent, broker, or

[140] For purposes of this proposal, ''agency-level'' misconduct or noncompliance refers to misconduct or noncompliance with HHS Exchange standards and requirements under § 155.220 associated with an eligibility application or enrollment transaction that lists an agency's NPN or that the agency was involved in or facilitated the submission of, or misconduct or noncompliance with HHS Exchange standards and requirements under § 155.220 that involves the agency's lead agent(s) or that the agency endorsed or is otherwise involved in.

[141] The term ''lead agent'' refers to any person who registers and/or maintains a business with a State and/or any person who registers a business National Producer Number (NPN) with the Exchange, who typically is an executive or person with a leadership role within an agency.

[142] The term also includes an agent or broker direct enrollment technology provider. See § 155.20.

[143] There are currently three Exchange Agreements with CMS that extend to agents or brokers assisting consumers in the FFEs and SBE–FPs: (1) the Agent Broker General Agreement for Individual Market FFEs and SBE–FPs, (2) the Agent Broker Privacy and Security Agreement for Individual Market FFEs and SBE–FPs, and (3) the Agent Broker SHOP Privacy and Security Agreement. Web-brokers assisting consumers in the FFEs and SBE–FPs are required to sign the Web-broker General Agreement, and web-brokers who are primary Enhanced Direct Enrollment (EDE) entities that assist consumers in the FFEs and SBE–FPs are required to sign the EDE Business Agreement and the Interconnection Security Agreement.

[144] In addition, each individual agent or broker who wishes to include the business entity NPN on Exchange eligibility applications must also complete the annual registration process, take the required trainings, and sign the applicable Exchange Agreements with CMS for the applicable plan year using their individual NPN.

[145] See supra note 138.

web-broker to assess their compliance with the applicable requirements of § 155.220.[146] Section 155.220(g) sets forth standards for suspension and termination of the agent's, broker's, or web-broker's Exchange Agreements for cause, which ends their participation in the FFEs.[147] These enforcement actions may be taken in three situations: (1) for specific findings or patterns of noncompliance,[148] (2) failure to maintain proper licensure in all States where the agent, broker, or web-broker is assisting consumers,[149] and (3) for engaging in fraud or abusive conduct.[150] Section 155.220(k) sets forth penalties other than suspension or termination of the agent's, broker's, or web-broker's Exchange Agreements for the current plan year. If an agent, broker, or web-broker fails to comply with the requirements of § 155.220, HHS may deny an agent, broker, or web-broker the right to enter into Exchange Agreements in future years [151] or impose a civil money penalty as described in § 155.285.[152] Lastly, HHS may immediately impose a system suspension against an agent or broker if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems.[153] System suspensions differ from Exchange Agreement suspensions because they prevent the agent or broker from utilizing Direct Enrollment (DE) platforms to enroll consumers but do not prevent them from enrolling consumers using *HealthCare.gov* or the Marketplace Call Center because they are still considered registered with the FFE.

Consistent with § 155.220(l), the FFE standards and requirements in § 155.220 also apply to agents, brokers, and web-brokers that assist with or facilitate enrollment in States with SBE–FPs.[154] Under the approach described in this preamble, leveraging the existing definitions of ''agent or broker'' and ''web-broker'' in § 155.20, we would also extend our authority to engage in compliance reviews and take enforcement actions to reach lead agents in both FFE and SBE–FP States who may be engaged in misconduct or are noncompliant with applicable standards and requirements in § 155.220. We believe this would better align our oversight and enforcement approach with how States regulate agencies.

The NPN is a unique identifier for an agent, broker, web-broker, or agency that the National Association of Insurance Commissioners assigns during the State licensing application process. The NPN can be recorded as part of the consumer's Exchange eligibility application and is used to track which individual agents, brokers, or web-brokers and agencies assisted Exchange consumers. QHP issuers use the NPN to identify the agent, broker, web-broker, or agency for compensation purposes. Either the NPN of the individual agent, broker, or web-broker assisting the consumer, or the business NPN of the agency, may be listed on the consumer's eligibility application submitted to an FFE or SBE–FP. In the most recent Open Enrollment survey, approximately 4 percent of respondents attested to using a business NPN for all their enrollments.[155] That means at least 640,000 enrollments [156] contained an NPN that did not belong to an individual agent, broker, or web-broker. The NPN, when provided, is a key identifying element in any compliance review under § 155.220(c)(5) or enforcement action by HHS under § 155.220(c)(4)(ii), (g)(1), (g)(3)(ii), (g)(5), (k)(1)(i), (k)(1)(ii), and (k)(3).

Under the approach described in this preamble, when information suggests there is agency-level misconduct or noncompliance, an investigation or compliance review would occur, and enforcement action may be taken. Any such compliance review, or enforcement action would be directed at the lead agent(s) and any other agent, broker, or web-broker who is discovered to be involved in the misconduct or noncompliant activity. When the misconduct or noncompliant activity is occurring at the agency-level, we believe it is appropriate for the lead agents to be subject to the compliance review, or enforcement action, in addition to the agents, brokers, or web-brokers working at or for an agency that may have been involved in the misconduct or noncompliant activity, as those lead agents are the individuals responsible for directing and/or overseeing their employees' and contractors' behavior and activity. Engaging in compliance reviews and taking enforcement actions against lead agents in these circumstances would ensure that the individuals who are directing and/or overseeing the misconduct or noncompliance are held accountable.

The first step (of two) we would take in determining if we would engage in a compliance review or enforcement action against the lead agents would be to determine if there appears to be agency-level endorsement of, or agency-level involvement in,[157] the misconduct or noncompliant behavior or activities of the agency's employees, contractors, or other agents, brokers, or web-brokers. Endorsement would involve the agency supporting or approving, either explicitly or implicitly, the relevant misconduct or noncompliant behavior or activities. Explicit endorsement may include written directives to agents, brokers, or web-brokers to engage in certain impermissible behavior, such as to submit eligibility applications without obtaining and documenting review and confirmation by the consumer (or their authorized representative) of the accuracy of the eligibility application information, as required by § 155.200(j)(2)(ii). Implicit endorsement may involve an agency continuing to employ an agent, broker, or web-broker whom they know has submitted consumer eligibility applications without first obtaining and documenting consumer consent, as required by § 155.200(j)(2)(iii).

Agency-level endorsement would indicate the misconduct or noncompliant behavior or activities are not random, isolated occurrences undertaken by a singular agent, broker, or web-broker and that the agency, and its lead agent(s), may be complicit in such misconduct or noncompliant behavior or activities. Determining if there is agency-level endorsement or involvement would involve review of

[146] 45 CFR 155.220(c)(5).

[147] We notify State Departments of Insurance when we suspend or terminate the Exchange Agreement(s) of an agent, broker, or web-broker under § 155.220(g), per § 155.220(g)(6). We also maintain and publish the Agent and Broker Federally-facilitated Marketplace (FFM) Registration Termination List, which allows QHP issuers, consumers, and other interested parties to search for NPNs associated with agents, brokers, and web-brokers whose Exchange Agreement(s) have been terminated or suspended. See *https://data.healthcare.gov/ab-suspension-and-termination-list.*

[148] 45 CFR 155.220(g)(1).

[149] 45 CFR 155.220(g)(3)(ii).

[150] 45 CFR 155.220(g)(5).

[151] 45 CFR 155.220(k)(1)(i).

[152] 45 CFR 155.220(k)(1)(ii).

[153] 45 CFR 155.220(k)(3). HHS also authority to temporarily suspend the ability of a web-broker to make its non-Exchange website available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction. See 45 CFR 155.220(c)(4)(ii).

[154] This includes the extension of the HHS authorities under § 155.220 to engage in compliance reviews and take enforcement actions with respect to misconduct or noncompliance by agents, brokers, or web-brokers in States with SBE–FPs.

[155] Open Enrollment Survey, conducted between January 29, 2024, and February 14, 2024.

[156] Based on the PY 2024 enrollment total of 16 million consumers.

[157] Examples, but not an exhaustive list, of agency-level involvement could be agency-level directives or materials provided to employees telling them to engage in such activity or the agency not stopping noncompliant behavior when the agency is aware of it.

several sources of information, some of which we discuss below. One source of information is data metrics involving lead agents, such as compliance data, to determine if we have received complaints directed towards an individual who is a lead agent for the agency in question. An agency whose lead agent is named in complaints, especially for unauthorized enrollments or other potentially fraudulent or noncompliant activity, could trigger a compliance review or enforcement action against the lead agent(s) at the agency, as it could indicate agency endorsement of or involvement in misconduct or noncompliant behavior or activities, including inaction by the agency to try to curb the misconduct or noncompliant behavior or activities. We would also look to see if complaints against a lead agent for an agency are similar to complaints received against the agency's other agents, brokers, or web-broker,[158] which could indicate agency-level endorsement or involvement in the misconduct or noncompliant behavior or activities.

Additionally, we would utilize system monitoring to identify potential misconduct or noncompliant behavior or activities. For example, we currently engage, and would continue to engage, in system monitoring by analyzing person searches on approved Classic DE and EDE partner sites to identify data trends that could indicate potential misconduct or noncompliant behavior or activities. Past investigations using system monitoring data have borne results that show a connection between potentially noncompliant, fraudulent, or abusive behavior and the trends we monitor. For example, we monitor the number of unsuccessful person searches on approved Classic DE and EDE partner sites because, in our experience, there is often a correlation between a high volume of unsuccessful person searches and noncompliant, fraudulent, or abusive behavior. The person search feature is intended to help agents, brokers, and web-brokers find consumer applications to prevent duplicate enrollments, but in our experience, bad actors use this feature to find applications and make plan changes or NPN changes without consumer knowledge or consent, negatively impacting the consumer and compliant agents, brokers, and web-brokers. However, because bad-acting agents, brokers, or web-brokers often do not have exact or complete consumer information, their person searches may not direct them to the consumer applications they are searching for, frequently leading them to run more unsuccessful searches using slightly different, yet incomplete or otherwise inaccurate, consumer information. Therefore, we monitor and would, under this proposal, continue to monitor, unsuccessful person searches on approved Classic DE and EDE partner websites to identify potential bad-actors.

Discovering agency-wide resources, such as company practices or directives, training manuals, or marketing material that suggests agency endorsement of or involvement in misconduct or noncompliant behavior or activities is another source of information we would use to determine whether to engage in a compliance review or take an enforcement action against the lead agents or other agents, brokers, or web-brokers who may be involved in the misconduct or noncompliant behavior or activities. We have seen agency-wide resources, such as training manuals or marketing documents, that contain information, promotions, or sales tactics suggestive of agency endorsement of or involvement in misconduct or noncompliant behavior or activities. For example, as part of compliance investigations and enforcement actions, we have seen agency documentation instructing agents and brokers who work at the agency to fabricate enrollee or applicant incomes on eligibility applications submitted to the FFEs or SBE–FPs to ensure the enrollee or applicant has a zero-dollar policy.[159] This can lead to consumers being enrolled in QHPs offered through Exchanges with zero-dollar premiums without their knowledge or consent. This, in turn, can lead to consumers owing money to the IRS during tax reconciliation because they were receiving APTC amounts but were not aware of this because their monthly premium was zero dollars.[160] [161]

Additionally, as part of these investigations and actions, we have reviewed agency procedures and directives instructing agents and brokers who work at the agency to not speak with the enrollee or applicant prior to enrolling them in a plan.[162] Not speaking with enrollees or applicants prior to submitting an enrollment may cause the consumer to receive incorrect APTC amounts, which the consumer will have to repay in the future, or may cause a consumer to receive data matching issues (DMIs), which, if left unresolved, can lead to loss of coverage.[163] Upon eligibility application submission, certain consumer data is checked against trusted data sources to ensure a match between what is in the application submission and the information HHS receives from the trusted data source(s). If the trusted data source does not have the consumer data or the data is inconsistent with the information provided on the application, a DMI is generated. A non-exhaustive list of DMIs include the Annual Income DMI, Citizenship/Immigration DMI, and American Indian/Alaskan Native Status DMI. Certain DMIs may lead to loss of Exchange coverage, including a Citizenship/Immigration DMI, which occurs when the consumer is unable to verify an eligible citizenship or lawful presence status.

Once we determined there is information or evidence suggesting there may be agency-level endorsement of or involvement in misconduct or noncompliant behavior or activities, we would then determine if the agency was involved in or facilitated the submission of the consumer's eligibility application or enrollment to the FFEs or SBE–FPs. This would also inform our determination of whether to engage in a compliance review or take enforcement action against the lead agent(s) or other agents, brokers, or web-brokers who may be involved in the misconduct or

[158] We would look at agent, broker, and web-broker email addresses or other submitted information, such as consent documentation or the NPN listed on the Exchange eligibility application, to help discern if there is a connection or relationship between an agent, broker, or web-broker and an agency.

[159] Fabricating an individual's income violates §§ 155.220(j)(2)(ii) and (j)(2)(ii)(E), which generally state that agents, brokers, and web-brokers must ''Provide the Federally-facilitated Exchanges with correct information . . .'' and household income projections must only be submitted when ''. . . the consumer or the consumer's authorized representative . . . has knowingly authorized and confirmed as accurate.'' The same standards and requirements apply to SBE–FP States. See 45 CFR 155.220(l).

[160] Appleby, J. (2024, May 7). *How the government is trying to stop rogue brokers from plaguing ACA enrollees.* KFF News, *https://www.npr.org/sections/health-shots/2024/05/07/1249417648/aca-health-insurance-brokers-obamacare-stop-fraud.*

[161] Consumers who find errors on their Form 1095–A, which contains information on APTC received, should contact the Marketplace Call Center to report any errors and discuss next steps for resolution. Additional information can be found here: *https://www.healthcare.gov/taxes/.*

[162] Failing to speak with the enrollee or applicant prior to enrolling them in a QHP offered on the Exchange violates § 155.220(j)(2)(ii)(A), which states eligibility application information must be ''reviewed by and confirmed to be accurate by the consumer . . .'' prior to submission. It also calls in question whether the agent, broker, or web-broker complied with the requirement in § 155.220(j)(2)(iii) to obtain and document the consumer's consent prior to assisting the consumer with the Exchange application and enrollment.

[163] For information on how to address any tax implications of APTC, consumers should refer to resources available at: *https://www.healthcare.gov/taxes/.*

noncompliant behavior or activities. Determining if the agency was involved in or facilitated the submission of the consumer's eligibility application or enrollment to the FFEs or SBE–FPs would involve looking at the agency's business practices and what resources it provides its agents, brokers, or web-brokers. In our experience, the more resources an agency allocates to supporting the ability of an agent, broker, or web-broker to enroll enrollees and applicants, the more indicative it is that the agency facilitates the submission of the eligibility application and enrollments to an FFE or SBE–FP. For example, if an agency provides an agent, broker, or web-broker with a training program, an email address with an agency domain, and access to other agency resources that support enrollment, such as a call center that intakes potential consumers to gather basic information, these are all indications the agency wants to make enrollments easier for the agent, broker, or web-broker and that the agency facilitates the submission of Exchange applications and enrollments. As previously noted, the inclusion of the business NPN is another clear indication of the agency's involvement in the submission of the Exchange application or enrollment transaction. This would be another critical piece of information that we would consider as we determine whether to engage in a compliance review or take enforcement action against the lead agent(s) or other agents, brokers, or web-brokers who may be involved in the misconduct or noncompliant behavior or activities.

We seek comment on these proposals. In particular, we are interested in comments from States as to the specific or unique characteristics of their agency oversight policies and procedures, including how they define or describe the term ''lead agent,'' or whatever term of art each State uses to capture our definition of ''lead agent'' in this preamble, as well as suggestions from States for ways to enhance collaboration and alignment of our oversight and enforcement of agencies that assist consumers applying for and enrolling in QHPs through the FFEs and SBE–FPs. We are also interested in comments from Classic DE and EDE partners, issuers, and other interested parties regarding whether we should consider an agent, broker, or web-broker that allows their NPN to be used by other agents, brokers, or web-brokers to be a lead agent and potentially held responsible for misconduct or noncompliant behavior or activities committed by another agent, broker, or web-broker using their NPN.

b. System Suspension Authority

We propose to amend § 155.220(k)(3), which outlines our authority to immediately suspend an agent's or broker's ability to transact information with the Exchange if we discover circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is sufficiently remedied or sufficiently mitigated to HHS' satisfaction. Specifically, we propose to add language to reflect that § 155.220(k)(3) system suspensions may be imposed in instances in which we discover circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260,[164] until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. We believe these amendments are necessary and appropriate Exchange program integrity measures to support the efficient administration of Exchange activities, reduce fraud and abuse, and protect Exchange applicant or enrollee personally identifiable information (PII).

Section 1312(e) of the ACA provides the Secretary with authority to establish procedures under which a State may allow agents or brokers to (1) enroll individuals and employers in any QHPs in the individual or small group market once the plan is offered through an Exchange in the State; and (2) assist individuals in applying for PTC and CSRs for plans sold through an Exchange. In addition, section 1313(a)(5)(A) of the ACA directs the Secretary to provide for the efficient and non-discriminatory administration of Exchange activities and to implement any measure or procedure the Secretary determines is appropriate to reduce fraud and abuse. Section 1321(a) of the ACA provides broad authority to the Secretary to establish standards and issue regulations to implement the statutory requirements related to Exchanges, QHPs, and other components of title I of the ACA, which includes sections 1312 and 1313. Section 1321(a) of the ACA also provides the Secretary with authority to implement other requirements as the Secretary determines appropriate. In prior rulemakings, we used these authorities to adopt § 155.220, which establishes standards and requirements applicable to agents, brokers, and web-brokers assisting individuals, employers, or employees with enrollment in QHPs offered through the FFEs, including the system suspension authority in § 155.220(k)(3). Consistent with § 155.220(l), the FFE standards and requirements in § 155.220 also apply to agents, brokers and web-brokers that assist with or facilitate enrollment in States with SBE–FPs.[165]

As we explained in the 2020 Payment Notice,[166] to promote information technology system security in the FFEs and SBE–FPs, including the protection of consumer data, we codified paragraph § 155.220(k)(3) to capture HHS' authority to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.[167] We explained this provision was necessary and appropriate to ensure that HHS can take immediate action to stop unacceptable risks to Exchange operations or systems posed by agents and brokers, as well as take immediate action to protect sensitive consumer data.[168] This provision currently applies to agents and brokers who, once registered under § 155.220(d)(1), obtain credentials that provide access to Exchange systems that may be misused in a manner that threatens the security of the Exchange's operations or information technology systems. When an agent's or broker's ability to transact information with the Exchange is

[164] Section 155.220(d)(3) requires agents and brokers to enter into a Privacy and Security Agreement pursuant to which they agree to comply with Exchange privacy and security standards adopted consistent with § 155.260. There are two Privacy and Security Agreements between CMS and the agent, broker, and web-broker for FFEs and SBE–FPs: (1) one is for the individual market FFEs and SBE–FPs, and (2) one is for the FF–SHOPs and SBE–FP–SHOPs.

[165] This includes the extension of the system suspension authority under § 155.220(k)(3).

[166] 84 FR 17517. Also see the 2020 Payment Notice proposed rule, 84 FR 272.

[167] This is similar to the authority captured at § 155.221(e) that applies to DE entities and permits HHS to immediately suspend the DE entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

[168] 84 FR 17517. Also see the 2020 Payment Notice proposed rule, 84 FR 272.

suspended under this authority, they remain registered with the FFEs and are authorized to assist FFE and SBE–FP consumers using the Exchange (or side-by-side) Pathway [169] and the Marketplace Call Center, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g).[170]

We propose to amend § 155.220(k)(3) to reflect that HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.[171] We are pursuing these amendments in the interest of transparency and to more clearly capture in regulation when HHS may invoke this authority. As noted above, we also believe these are necessary and appropriate Exchange program integrity measures to support the efficient administration of Exchange activities, reduce fraud and abuse, and protect Exchange applicant or enrollee PII.

We continuously monitor for behaviors or activities related to Exchange operations or access to Exchange systems and enrollee or applicant PII that we believe, based on our experience overseeing agents and brokers on the FFEs and SBE–FPs, may be indicative of misconduct or noncompliance with applicable HHS Exchange standards or requirements. Our experience overseeing agents and brokers on the FFEs and SBE–FPs includes past completed agent, broker, and web-broker investigations and enforcement actions, and observations of behavior by agents and brokers that may not comply with the standards of conduct at § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260 and that could endanger the accuracy of Exchange eligibility determinations, applicant or enrollee PII, or Exchange operations or systems in a number of ways.

A non-exhaustive list of agent or broker data we monitor to identify behaviors or activities that may be indicative of misconduct or noncompliance with applicable HHS Exchange standards or requirements includes: (1) the number of Exchange transactions submitted to the FFEs or SBE–FPs to change enrollee or applicant eligibility application information or plan selections, (2) the volume of person search activities, (3) the number of submitted eligibility applications with missing Social Security Numbers (SSNs), (4) the number of enrollments submitted within a specified time-frame, and (5) the volume of submitted eligibility applications with NPN changes. We also review and consider complaints from enrollees, applicants, and other individuals or entities concerning agent and broker activities.[172]

Once we receive a complaint or identify concerning or anomalous data, we review the complaint and/or data to determine if there is information that suggests the impacted enrollees or applicants may have authorized the agent or broker to submit an Exchange eligibility application, or an update to an existing enrollment, on their behalf. We then review the available documentation and application details and may contact the agent or broker and interview Exchange enrollees or applicants to gather more information. Depending on the results of this preliminary investigation, agents or brokers may be provided additional education and technical assistance, or we may implement a system suspension under § 155.220(k)(3) if we discover circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems.

There are different factors we consider when deciding whether to implement a system suspension under § 155.220(k)(3) or offer technical assistance. These factors include the number of times that our data, including complaints we receive, indicate that an agent or broker may have engaged in misconduct or noncompliance with applicable HHS Exchange standards or requirements, the number of consumers impacted by their suspected misconduct or noncompliant behavior or activities, and the severity of the alleged misconduct or noncompliant behavior or activities. We would continue these practices for system suspensions under the proposed updates in this rule to § 155.220(k)(3), which would expand the bases for imposing a system suspension to include situations that pose unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange applicants, and Exchange enrollees. This proposed amendment to § 155.220(k)(3) aligns with the approach outlined in the 2020 Payment Notice (84 FR 17517) and is in response to misconduct and noncompliant behavior and activities by agents and brokers that we have observed in connection with our oversight of the FFEs and SBE–FPs. This proposal is designed to promote information technology system security in the FFEs and SBE–FPs, including the protection of consumer data, reduce fraud and abuse, and support the efficient administration of Exchange activities.

Consistent with the existing framework, in circumstances where we would impose a system suspension under the proposed amendments to § 155.220(k)(3), we would notify the agent or broker of the suspension and they would have an opportunity to submit evidence and information or to demonstrate that the circumstances of the incident, breach, or noncompliance are sufficiently remedied or mitigated to HHS' satisfaction to warrant lifting the suspension to reinstate their system access. We would review such evidence and information submitted by the agent or broker to determine if the circumstances of the incident, breach, or noncompliance are sufficiently remedied or mitigated to warrant lifting the suspension to reinstate their system access. For example, we anticipate receiving documentation of consumer consent and/or review and confirmation of the accuracy of the Exchange eligibility application information and assessing whether the documentation complies with § 155.220(j)(2)(ii) and (iii) for consumers cited in the suspension notice from agents and brokers we system suspend under § 155.220(k)(3). If such evidence or information sufficiently remedies or mitigates the incident, breach or noncompliance to our satisfaction, we would lift the

[169] For more information on the Exchange Pathway, please see, CMS. (2016, Nov. 8). *Health Insurance Marketplace Guidance: Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplace. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Role-of-ABs-in-Marketplace_Nov-2016_Final.pdf.*

[170] 84 FR 17517.

[171] We are not proposing to add a reference to web-brokers as part of these amendments to § 155.220(k)(3) because, as DE entities, web-brokers are subject to the system suspension authority at § 155.221(e). See § 155.221(a)(2). This is similar to the authority captured at § 155.221(e) that applies to DE entities and permits HHS to immediately suspend the DE entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

[172] Complaints may be submitted to the Marketplace Call Center. See *https://www.cms.gov/files/document/agent/broker-help-desks.pdf.*

suspension and reinstate Exchange system access for the agent or broker.

In cases where such evidence and information does not sufficiently remedy or mitigate the circumstances of the incident, breach or noncompliance to HHS' satisfaction (including situations where there is no response from the agent or broker), we would not lift the suspension under § 155.220(k)(3) to reinstate the agent's or broker's system access and would pursue a suspension or termination of the agent's or broker's Exchange Agreements under § 155.220(g). As previously noted, agents and brokers whose ability to transact information with the Exchange is suspended under § 155.220(k)(3) remain registered with the FFEs and are authorized to assist consumers using the Exchange (or side-by-side) pathway and the Marketplace Call Center, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g).

We are pursuing these amendments at this time in light of recent increases in behavior by agents and brokers that indicate potential violations of § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260 and endangers applicant or enrollee PII or Exchange program integrity in a manner that poses unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems.

Since the start of PY 2024 Open Enrollment, we have seen an increase in complaints from enrollees, applicants, and other individuals and entities to the Agent/Broker Help Desk regarding enrollments submitted without enrollee or applicant consent, enrollee or applicant eligibility applications submitted with incorrect information and without enrollee or applicant review or confirmation of the eligibility application information, and changes to enrollee or applicant eligibility applications made without enrollee or applicant consent.[173] A significant portion of these complaints have involved unauthorized changes to the plans in which enrollees or applicants were enrolled, impacting the ability of enrollees or applicants to utilize their desired coverage and access care.[174]

Unauthorized plan changes may harm enrollees or applicants by removing them from their selected plan and placing them in another plan that may not provide coverage that meets their needs (for example, different plans can have different formularies and provider networks). Unauthorized enrollments can also involve situations where individuals are enrolled in an Exchange plan without having an existing Exchange plan. Being enrolled in an Exchange plan, including in the case of an unauthorized enrollment, may impact a consumer's future ability to enroll in health insurance through the Exchange or enroll in Medicare or Medicaid, as a consumer may not enroll in more than one plan simultaneously. Unauthorized enrollments may also create premium costs for the consumer if the unauthorized enrollment is in a non-zero-dollar premium plan. Unauthorized plan changes and enrollments cost the consumer time to learn about and resolve the discrepancy and either (1) unenroll from a plan they did not want, or (2) change the plan to one that better meets their needs.

Additionally, submission of eligibility applications with inaccurate enrollee or applicant data, such as an incorrect income, may cause harm by providing the enrollee or applicant with an incorrect APTC amount. An incorrect APTC amount can result in a consumer erroneously receiving a zero-dollar monthly premium. Because the consumer does not receive monthly billing notifications due to the zero-dollar premiums, they may not know they were enrolled or that their eligibility application information was incorrect. However, once the consumer files their taxes, a reconciliation may reveal that the consumer must repay the incorrect APTC amount they were receiving. By their nature, these unauthorized enrollments and plan changes involve the misuse of enrollee or applicant PII, and they threaten the efficient administration of the Exchange and the accuracy of Exchange eligibility determinations.

Our experience monitoring compliance with the new requirements in § 155.220(j)(2)(i), (ii), and (iii) has also shown that agents, brokers, and web-brokers are engaging in misconduct or noncompliant behavior or activities. For example, their consumer consent and eligibility application information review documentation often lacks the required content specified in § 155.220(j)(2)(ii) or (iii) that demonstrates the applicant or enrollee has taken an action to provide consent or confirm the accuracy of the eligibility application information prior to submission to the Exchange. For example, we have seen consent documentation that solely lists numbers that the agent, broker, or web-broker claims tie back to the consumer's IP address, which we cannot verify and does not meet the consent documentation requirements of § 155.220(j)(2)(iii). Additionally, we have received consent documentation that is merely a name, typed using a cursive script, with no indication the consumer took an action to confirm their consent to the assistance provided by the agent, broker, or web-broker, such as a text message response, email response, or signature.[175] The proposed amendments to § 155.220(k)(3) to permit immediate system suspensions would support HHS' efforts to take immediate action to prevent further enrollee, applicant, Exchange operational, Exchange information technology, or Exchange program integrity harm caused by agents and brokers engaged in these types of misconduct.

Though we believe our current authority in § 155.220(k)(3) allows HHS to implement system suspensions broadly based on circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems, in light of the increasing complaints about unauthorized enrollments, we propose amendments to § 155.220(k)(3) to increase transparency concerning the reach and application of system suspensions and more accurately capture in regulation when HHS may invoke this authority. These proposed amendments would allow HHS to immediately respond to discovered risks to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems. They would also provide agents and brokers with an increased understanding of our

[173] CMS. (2024, July 19). *CMS Statement on System Changes to Stop Unauthorized Agent and Broker Marketplace Activity. https://www.cms.gov/newsroom/press-releases/cms-statement-system-changes-stop-unauthorized-agent-and-broker-marketplace-activity.*

[174] When consumers call the Marketplace Call Center to report unauthorized enrollments, we resolve their complaints through a combination of the following: (1) we review the complaint to verify that the consumer's plan switch was unauthorized and identify the plan that the consumer wants to be enrolled in; (2) we instruct the issuer offering the plan the consumer wants to be enrolled in to reinstate the consumer's enrollment in that plan as if it had not been terminated. The insurer is instructed to cover all eligible claims incurred and accumulate all cost sharing toward applicable deductibles and annual limits on cost sharing; and/or (3) consumers receive updated tax forms and information via a 1095–A that is generated by HHS and which the enrollee sends to the IRS to prevent adverse tax implications as a result of the unauthorized plan switch activity.

[175] A typed name using a cursive script, alone, makes it impossible for CMS to determine if the consumer, or their authorized representative, provided the consent and typed the signature. In these situations, supplemental documentation is required for CMS to assess compliance with the consent requirements of § 155.220(j)(2)(iii).

approach to implement system suspensions. The proposed amendments would also better encapsulate the original intent of the § 155.220(k)(3) suspension authority, which included protecting against unacceptable risk to consumer Exchange data.

We note that the types of misconduct or noncompliant behaviors or activities that could lead to a system suspension under § 155.220(k)(3) could also lead to an enforcement action under § 155.220(g). However, there are important distinctions between these authorities. For example, system suspensions under § 155.220(k)(3) allow HHS to immediately suspend an agent or broker's system access. These suspensions differ from suspensions or terminations under § 155.220(g) because they do not suspend or terminate the agent's or broker's Exchange Agreement(s).[176] Rather, they prevent agents or brokers from submitting Exchange applications and enrollments through the Direct Enrollment Pathways, whether Classic DE or EDE. However, while a system suspension is in place, the agent or broker remains registered with the FFEs, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g). As such, a system suspension does not prohibit the agent or broker from enrolling enrollees or applicants via the Marketplace Call Center on a three-way call with the enrollees or applicants or side-by-side with an enrollee or applicant on *HealthCare.gov* (also known as the ''Exchange Pathway'').[177] In cases where there is imminent danger to applicants' or enrollees' PII or to Exchange program integrity in such a manner that poses unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems from the misconduct of agents, brokers, or web-brokers, system suspensions under the proposed amendments to § 155.220(k)(3) would provide a more immediate action to protect applicants' or enrollees' PII and the efficient administration of the Exchange, as well as reduce potential fraud and abuse.

In contrast, an enforcement action under § 155.220(g) to suspend or terminate an agent's, broker's, or web-broker's Exchange Agreement(s) results in the agent, broker, or web-broker no longer being registered with the FFEs.[178] When an agent's, broker's, or web-broker's Exchange Agreements are suspended, or following the termination of the agent's, broker's, or web-broker's Exchange Agreements, the agent, broker, or web-broker is also no longer permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an FFE or SBE–FP, or assist individuals in applying for APTC and CSRs for QHPs. As such, these agents, brokers, and web-brokers cannot submit Exchange applications and enrollments through any of the available pathways—through Classic DE, EDE, the Marketplace Call Center, and/or through the Exchange pathway.

Though we would only initiate enforcement action under § 155.220(k)(3) against agents and brokers based on data or other information that suggest noncompliance or misconduct, we recognize that data or other information could suggest there is noncompliance or misconduct by a compliant agent or broker. For example, in some instances, this could occur if an agent or broker works largely or exclusively with a specific group of consumers, including those who live in low-income communities, communities where life changes necessitating eligibility application changes may be more common, or communities where some consumers may not have SSNs but are nonetheless eligible for Exchange coverage. Consistent with the existing framework, when pursuing system suspensions under § 155.220(k)(3), as proposed to be amended, agents and brokers would be notified of the system suspension and would have an opportunity to submit evidence or other information (such as documentation of consumer consent and review of the eligibility application information that is compliant with § 155.220(j)(2)(ii) and (iii)), to demonstrate that the circumstances of the incident, breach, or noncompliance concerns are sufficiently remedied or mitigated to HHS' satisfaction to merit reinstatement of their system access. Where there is clear evidence of compliance, compliant agents and brokers would be able to quickly respond to or otherwise remediate the risks identified by HHS that led to the system suspension under § 155.220(k)(3) such that their system access could be reinstated more swiftly than the lifting of a suspension or reinstatement of an agent's or broker's Exchange Agreement(s) following an enforcement action under § 155.220(g).

We seek comment on this proposal.

c. Model Consent Form Updates

We are proposing to modify the Model Consent Form that was created as part of the 2024 Payment Notice (88 FR 25809 through 25811).[179] Our proposed modifications include updating the Model Consent Form to include a section for documentation of consumer review and confirmation of the accuracy of their Exchange eligibility application information under § 155.220(j)(2)(ii)(A)(1)–(2), as well as scripts agents, brokers, and web-brokers could use when meeting the requirements codified at § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C) via an audio recording.

Agents, brokers, and web-brokers are required to obtain consumer consent prior to assisting with and facilitating enrollment in coverage through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs. Until we finalized new requirements related to consumer consent in the 2024 Payment Notice, there was no mandate to document the receipt of consent of the consumer or their authorized representative, or to maintain such documentation. The absence of a consent documentation requirement led to disputes between consumers and agents, brokers, and web-brokers that were difficult for us to adjudicate because neither party had documentary proof of consent. In the 2024 Payment Notice (88 FR 25809 through 25811), we finalized regulations

[176] Consistent with § 155.220(d), there are currently three Exchange Agreements with CMS that extend to agents or brokers assisting consumers in the FFEs and SBE–FPs: (1) the Agent Broker General Agreement for Individual Market FFEs and SBE–FPs, (2) the Agent Broker Privacy and Security Agreement for Individual Market FFEs and SBE–FPs, and (3) the Agent Broker SHOP Privacy and Security Agreement. Web-brokers assisting consumers in the FFEs and SBE–FPs are required to sign the Web-broker General Agreement, and web-brokers who are primary Enhanced Direct Enrollment (EDE) entities that assist consumers in the FFEs and SBE–FPs are required to sign the EDE Business Agreement and the Interconnection Security Agreement. In addition, each individual agent or broker who wishes to include the business entity NPN on Exchange eligibility applications must also complete the annual registration process, take the required trainings, and sign the applicable Exchange Agreements with CMS for the applicable plan year using their individual NPN.

[177] In this pathway, registered agents and brokers help a consumer obtain an eligibility determination and select a plan directly on *HealthCare.gov*. The consumer creates an account, logs in to the *HealthCare.gov* website with a consumer account, and ''drives'' the process; the agent or broker does not log in to *HealthCare.gov*. Generally, the Exchange Pathway requires the agent or broker to be sitting side-by-side with the consumer because the consumer must sign in to *HealthCare.gov* without sharing their log-in credentials with the agent or broker.

[178] See § 155.220(g)(4) and (5)(iii).

[179] CMS. (2022, December 14). CMS Model Consent Form for Marketplace Agents and Brokers. PRA package (CMS–10840, OMB 0938–1438). *https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf.*

requiring receipt of consent of the consumer or their authorized representative to be documented.[180] Under these regulations, the consent documentation must contain certain minimum elements as enumerated in § 155.220(j)(2)(iii)(B) and must be retained by the assisting agent, broker, or web-broker for a minimum of 10 years and produced to HHS upon request in response to monitoring, audit, and enforcement activities pursuant to § 155.220(j)(2)(iii)(C). Our goal in codifying these consent documentation requirements was to minimize the risk of fraudulent activities, such as unauthorized enrollments, and help us resolve disputes and adjudicate claims related to the provision of consumer consent.

We also finalized regulations in the 2024 Payment Notice (88 FR 25804 through 25809) requiring agents, brokers, and web-brokers assisting with and facilitating enrollment in coverage through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission.[181] Under these regulations, this documentation must contain certain minimum elements as enumerated in § 155.220(j)(2)(ii)(A)(1) and must be retained by the assisting agent, broker, or web-broker for a minimum of 10 years and produced to HHS upon request in response to monitoring, audit, and enforcement activities pursuant to § 155.220(j)(2)(ii)(A)(2). Our goal in codifying these requirements was to minimize the risk of fraudulent activities, such as providing false information to the Exchange, help us resolve disputes and DMIs and adjudicate claims related to inaccurate eligibility information on submitted applications, and ensure consumers receive accurate eligibility determinations and do not receive incorrect APTC determinations, which may result in consumers owing money during tax reconciliation.

The Model Consent Form [182] created and provided to agents, brokers, and web-brokers on June 30, 2023, has been used by agents, brokers, and web-brokers, either as is or as a starting point for creating their own consent documentation. However, no Model Consent Form was created for agents, brokers, and web-brokers to use to meet the documentation of consumer review and confirmation of the accuracy of the eligibility application information requirements enumerated in § 155.220(j)(2)(ii)(A)(1). Since the 2024 Payment Notice requirements went into effect, agents, brokers, and web-brokers have asked us to provide a model documentation that they could use to meet these requirements under § 155.220(j)(2)(ii). We are proposing to update the Model Consent Form to include a section for documentation of consumer review and confirmation of the accuracy of their Exchange eligibility application information in response to these requests. This proposed addition to the Model Consent Form is meant to provide clarity to agents, brokers, and web-brokers on how to meet the regulatory requirements under § 155.220(j)(2)(ii) and help them comply with this regulation by providing a standardized form they may use to do so. Furthermore, we believe providing a clearly written Model Consent Form would provide more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with § 155.220(j)(2)(ii).

Because the requirements of § 155.220(j)(2)(ii)(A) and (j)(2)(iii) can be met via an audio recording, we are also proposing to create appendices to the Model Consent Form that would contain scripts agents, brokers, and web-brokers may use to document compliance with these requirements via an audio recording. Our goal is to provide agents, brokers, and web-brokers who assist consumers verbally with guidance on meeting the consent and eligibility application review documentation requirements contained in § 155.220(j)(2)(iii) and (j)(2)(ii)(A), respectively, similar to how the current Model Consent Form helps agents, brokers, and web-brokers documenting consent via a physical document with handwritten signatures demonstrate compliance with the new consent documentation requirements.

The proposed scripts, to the extent they are utilized by agents, brokers, and web-brokers, would help ensure agents, brokers, and web-brokers are following the regulatory requirements when enrolling consumers. We believe this would reduce consumer harm by reducing unauthorized enrollments, which can result in financial harm if a consumer receives an improper APTC amount upon enrollment. We also believe this proposal would clarify and simplify how regulated entities can meet regulatory requirements. This proposal does not involve any revisions to § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C). If finalized as proposed, it would not be mandatory for agents, brokers, or web-brokers to use the amended Model Consent Form or new scripts to comply with the requirements set forth in § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C).

We seek comment on these proposals.

3. Requirement for Notification of Tax Filers and Consumers Who Have Failed To File and Reconcile APTC for Two Consecutive Tax Years (§ 155.305)

As part of the 2024 Payment Notice, we changed the FTR process such that an Exchange may only determine enrollees ineligible for APTC due to their FTR status after a tax filer (or a tax filer's spouse, if married) has failed to file a Federal income tax return and reconcile their APTC for 2 consecutive years (specifically, years for which tax data will be utilized for verification of household income and family size). However, in that rule, we did not impose a requirement for Exchanges to notify enrollees or their tax filers that the applicable tax filer failed to file and reconcile. In the 2025 Payment Notice, we imposed a requirement for Exchanges to send direct or indirect notices for the first year in which the tax filer was determined to have failed to file and reconcile. We are now proposing to revise § 155.305(f)(4) to require Exchanges to send a direct or indirect notice (as defined below) to enrollees or their tax filers who have not filed their Federal income tax return and reconciled their APTC for two consecutive tax years.

To our knowledge, when FTR operations were conducted in prior years before the new two-year process that was implemented as part of the 2023 Payment Notice (87 FR 27208), it was the practice of Exchanges to send notices to enrollees or their tax filers (or both) who were at risk of being determined ineligible for APTC due to failing to file and reconcile APTC for the previous tax year. Enrollees or their tax filers would be sent notices after the initial identification of FTR status prior to Open Enrollment and/or during the FTR Re-check process, depending on the process of the Exchange. In addition, it has also been the practice of Exchanges to notify enrollees or their tax filers (or both) of their FTR status when they attest that they have filed their Federal income tax return and reconciled APTC, but IRS data has not been updated to reflect their compliance with the requirement to file and reconcile. FTR Re-check is the post

[180] 45 CFR 155.220(j)(2)(iii).

[181] See § 155.220(j)(2)(ii).

[182] CMS. (2022, December 14). *CMS Model Consent Form for Marketplace Agents and Brokers.* PRA package (CMS–10840, OMB 0938–1438). *https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf.*

Open Enrollment verification process for consumers with either a one-tax year or two-tax year FTR status. Exchanges using the Federal eligibility and enrollment platform begin FTR Re-check operations by cross referencing past FTR statuses, consumers' attestations made on the current plan year's applications if applicable, and IRS income data to confirm whether tax filers filed their Federal income tax returns and reconciled APTC for one or both of the most recent tax years for which the IRS provides data to Exchanges through the Federal Data Services Hub. FTR Re-check generally happens after Open Enrollment ends on January 15 for Exchanges using the Federal eligibility and enrollment platform.

We are proposing to require, consistent with the notice requirement in § 155.305(f)(4)(i), that, for a consumer identified as having a two-tax year FTR status, Exchanges provide either a direct notification to the tax filer that the Exchange has determined that the tax filer or their spouse has failed to file and reconcile their APTC for two consecutive tax years (''direct notice''), or a notification to the consumer stating that they may be at risk of losing their APTC and educating them about the requirement to file their Federal income taxes and reconcile their APTC (''indirect notice or ''combined notice''). The proposed revisions would require Exchanges to send a direct notice or a combined notice for consumers identified as having both a one tax-year, and a two tax-year, FTR status. In addition to these notices, consumers who lose their APTC after the FTR Recheck process will also receive the eligibility determination notice (EDN) under § 155.330(e)(1)(ii).

This proposed requirement represents the minimum requirement for Exchanges to provide sufficient notice to enrollees or their tax filer (or both) about the need to file their Federal income tax return and reconcile APTC, and the risks of failing to do so. Consistent with operations before the COVID–19 pandemic, Exchanges on the Federal platform provide enrollees or their tax filers (or both) with more notifications that go above and beyond the minimum requirement, and they will continue to do so. Specifically, Exchanges on the Federal platform send out combined notices prior to Open Enrollment, and then again after FTR Recheck for both the one-tax year and two-tax year FTR populations. Tax filers who are identified as being in either a one-tax year or two-tax year FTR status prior to Open Enrollment, and then again after FTR Recheck, also receive direct notices. HHS encourages State Exchanges to adopt these best practices as well to provide multiple points of contact to the enrollee or tax filer (or both) on the requirement to file and reconcile their APTC to remain eligible for APTC. However, due to the concerns of interested parties about the difficulty required to notify both enrollees and tax filers, we are choosing to propose requiring only notifying either the consumer or the tax filer for the second tax year FTR population, and we acknowledge that most State Exchanges' current practice already involves multiple notifications for consumers who are at risk of losing their APTC. As the proposal only requires one notification to consumers in a two-tax year FTR status, similarly to the current rules only requiring one notice for one-tax year FTR status consumers, it is possible that Exchanges could choose to send this notice with Open Enrollment prior to the plan year where the enrollee may lose APTC or during the plan year in which the Exchange would remove APTC.

Therefore, we are proposing to add a section to § 155.305(f)(4)(ii) stating that if HHS informs an Exchange that APTC payments were made on behalf of either the tax filer or the tax filer's spouse, if applicable, for two consecutive tax years and they did not comply with the requirement to file an income tax return for those years as required by 26 U.S.C. 6011, 6012 and applicable regulations, then the Exchange must send a notice as directed in proposed subparagraphs (f)(4)(ii)(A) or (B) (or both). In proposed subparagraph (f)(4)(ii)(A), we propose to require an Exchange to send a notice directly to the tax filer informing the tax filer that they have been identified as failing to file and reconcile for two consecutive tax years, educating them about the requirement to file and reconcile APTC, and warning them that they are at risk for losing APTC eligibility because they, or their spouse, if applicable, did not file their Federal income tax return for two consecutive tax years. Exchanges that choose to send these direct notices must comply with statutory requirements to protect Federal tax information (FTI) per 26 U.S.C. 6103. For Exchanges on the Federal platform, these direct notices are sent via U.S. postal mail only, and no electronic copy of the notice is retained to protect FTI. Finally, we propose to add new subparagraph (f)(4)(ii)(B), which requires an Exchange to send an indirect notice to either the tax filer or their enrollee that does not disclose FTI but educates the enrollee or their tax filer on the requirement to file their Federal income tax return and reconcile APTC.

These proposed changes would ensure that either all tax filers or, if applicable, their enrollees who are identified as having an FTR status for two consecutive tax years would receive educational notices detailing the requirement to file and reconcile their APTC at least twice before losing their APTC eligibility; they would receive a notice for the first year they were found to be in an FTR status, and then again the second consecutive tax year they were found to have failed to file and reconcile their APTC.

As discussed in 2025 Payment Notice (89 FR 26299), we want to continue to ensure tax filers and enrollees are provided appropriate education on the requirement to file and reconcile their ATPC before being determined ineligible for APTC for failing to file and reconcile for a second consecutive tax year. Sample notices would be available at *https://www.cms.gov/marketplace/in-person-assisters/applications-forms-notices/notices.*

We seek comment on this proposal.

4. Timeliness Standard for State Exchanges To Review and Resolve Enrollment Data Inaccuracies § 155.400(d)(1)

We propose to add § 155.400(d)(1) to codify HHS guidance [183] that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange (hereinafter referred to as ''State Exchange issuer'') that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuer's enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.[184] This proposed policy aligns with the existing requirement at § 155.400(d) that a State Exchange must reconcile enrollment information with issuers and HHS no less than on a monthly basis. It also provides certainty for State Exchange issuers by providing a timeline for State

[183] CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf.*

[184] OMB Control No: 0938–1312 and 0938–1341.

Exchanges to act upon enrollment data inaccuracies submitted to the State Exchange by a State Exchange issuer that meets the requirements at § 156.1210(a)–(c).

Section 156.1210 generally requires State Exchange issuers to submit a description of all enrollment data inaccuracies, including those that impact APTC payments, to HHS or the State Exchange, as indicated by State Exchange guidance, in a manner and format specified by HHS or the State Exchange, within 90 calendar days of the date of a payment and collections report from HHS. At the same time, § 156.1210(b) also acknowledges that, in limited circumstances, HHS may consider inaccuracies received from a State Exchange issuer to resolve an enrollment data inaccuracy that was submitted after 90 calendar days when: (1) the State Exchange issuer notifies the State Exchange or HHS, as applicable, within 15 calendar days after identifying the inaccuracy; and (2) the State Exchange issuer's failure to identify the inaccuracy and submit to HHS or the State Exchange within the required 90 calendar day period was reasonable and not due to the issuer's misconduct or negligence.

Most recently, in the 2024 Payment Notice (88 FR 25886), we amended § 156.1210 to add paragraph (c), which provides a final deadline for issuers to submit data inaccuracies identified in payment and collections reports. Section 156.1210(c) specifies that to be eligible for resolution under § 156.1210(b), an issuer must describe inaccuracies before the end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates. Notwithstanding the above, and in alignment with obligations under the False Claims Act,[185] issuers must report overpayments to HHS or the State Exchange and timely repay any overpayment, regardless of when a payment error is identified, including after the 3-year deadline.[186]

Because State Exchanges provide the enrollment data that HHS uses as the basis of APTC payments to State Exchange issuers in the automated Policy-Based Payment (PBP) system, State Exchanges must update their enrollment data before HHS makes any PBP APTC payment adjustments to a State Exchange issuer. Therefore, the State Exchange issuer must work with its State Exchange to ensure resolution of any inaccuracy impacting APTC payment. If a State Exchange issuer is directed by its State Exchange to submit inaccuracies directly to HHS, the State Exchange issuer should follow those submission instructions, but any information HHS shares in response to the submission is informational. If the inaccuracy remains unresolved, the State Exchange issuer must follow up with its State Exchange to identify and rectify the reason for non-resolution. In accordance with § 155.400(b), a State Exchange must submit all enrollment data that HHS then uses to calculate APTC payments to State Exchange issuers. Therefore, in instances when a State Exchange does not timely address State Exchange issuer data inaccuracies, HHS cannot directly assist the State Exchange issuer in addressing these data inaccuracies.

This proposal would codify guidance in the document titled, ''Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges Frequently Asked Questions''.[187] This guidance directs State Exchanges to review descriptions of data inaccuracies submitted by State Exchange issuers, resolve them, and submit to HHS a description of the resolution of the inaccuracies when the State Exchange issuer submits a description of a data inaccuracy within the 90 calendar day deadline, or reasonably after the 90 calendar day deadline but before the 3-year deadline pursuant to § 156.1210(b) and (c). The guidance directs State Exchanges to submit the resolution of these inaccuracies to HHS via the State Based Marketplace Inbound File (SBMI) within 60 calendar days after receiving from a State Exchange issuer a description of a data inaccuracy that includes all the information that the State Exchange requires or requests to properly assess the inaccuracy. This proposed timeline for resolution of enrollment data inaccuracies would require State Exchanges to timely review and resolve enrollment data inaccuracies; clarify the resolution process for State Exchange issuers; and ensure the accurate payment of APTCs, as enrollment data is the basis of APTC payments to State Exchange issuers in the automated PBP system. If this proposal is finalized, to track the State Exchanges' efforts to meet the 60-calendar day requirement for submitting inaccuracies to HHS, we would consider modifying the State-based Marketplace Annual Reporting Tool (SMART) to have State Exchanges outline their processes for resolving data inaccuracies timely in accordance with this policy.

We solicit comments on this proposal.

5. Establishment of Optional Fixed-Dollar Premium Payment Threshold and Total Premium Threshold (§ 155.400(g))

We propose to codify a provision related to the premium payment threshold policies under § 155.400(g) that would allow additional issuer flexibility to decide when amounts collected from an enrollee would be considered to satisfy their obligation to pay the enrollee-responsible portion of the premium for certain purposes. Specifically, this would provide issuers with additional flexibility to not place an enrollee in a grace period for failure to pay the full amount of their portion of premiums due, and to not terminate enrollment through the Exchange after the applicable grace period ends without outstanding premiums being paid in full. This proposal would reduce the number of coverage terminations for enrollees who owe only a small amount of premium within the threshold. Specifically, we propose that issuers be permitted to set a fixed-dollar threshold of $5 or less, which would be adjusted for inflation. We are also considering permitting issuers to adopt a threshold that is based on the gross premium owed by the enrollee, rather than net premium. We also propose to modify the threshold of the existing premium payment threshold policy at § 155.400(g) for clarity.

Currently, issuers have the option under § 155.400(g) to adopt a percentage-based premium payment threshold which allows issuers to effectuate coverage in accordance with binder payment rules at § 155.400(e) for enrollees who pay an amount of the enrollee-responsible portion of the premium that is less than 100 percent but within the threshold (we have historically recommended a percentage equal to or greater than 95 percent).[188] This avoids triggering a grace period for non-payment under § 156.270(d) or a grace period under State rules, and may avoid terminating enrollment for non-payment of premiums. Under this policy, if the total amount of premium owed by an enrollee (including aggregate amounts over multiple

[185] See 88 Fed Reg, 25740, 25887 (''Consistent with section 1313(a)(6) of the ACA and 31 U.S.C. 3729, *et seq.,* payments made by, through, or in connection with an Exchange are subject to the False Claims Act if those payment include any Federal funds'').

[186] See 45 CFR 156.480 requiring State Exchange issues to maintain relevant records for 10 years.

[187] CMS. (2024, August 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf.*

[188] See CMS. (2023). *Federally-facilitated Exchange (FFE) Enrollment Manual.* Section 6.2. *https://www.cms.gov/files/document/ffe-enrollment-manual-2023-5cr-071323.pdf.*

months) exceeds the threshold set by the issuer, the issuer is required to place the enrollee in a grace period: either the grace period for enrollees receiving APTC described at § 156.270(d), or a grace period under State authority, as applicable. Any amount that is unpaid but within the reasonable premium payment threshold established by an issuer remains an amount owed by the enrollee and cannot be forgiven by the issuer.[189] Currently, this threshold must be a percentage, and it must be reasonable. We have stated that 95 percent or more of the enrollee-responsible portion of the premium would be a reasonable threshold.[190] This threshold must be applied uniformly to all enrollees.

In the 2017 Payment Notice (81 FR 12271 through 12272), in which HHS established the option for issuers to implement a percentage-based premium payment threshold, we received a comment requesting that issuers be allowed to establish a flat dollar amount threshold. At that time, we stated that we did not consider implementing such a threshold because there may be cases in which even a low flat dollar amount may represent a large percentage of an enrollee's portion of the premium less APTC (81 FR 12272).

However, after implementation of the percentage-based threshold, we have realized that the percentage-based premium threshold policy does not always adequately enable enrollees who owe small amounts of premium to avoid triggering a grace period or termination of enrollment through the Exchange. For example, an enrollee whose enrollee-responsible portion of the premium was $1 after APTC, and who failed to make a premium payment, would be placed into a grace period even if the issuer had adopted a 95 percent payment threshold, despite being delinquent by only $1. In an analysis of Exchange data for the 2023 Plan Year, we found that there were 81,383 total policies terminated for non-payment in which $5 or less was owed by the enrollee, representing approximately 5.4 percent of the total number of policies terminated for non-payment that year. In addition, 102,728 policies in which enrollees owed premiums of $5.01 to $10 were terminated for non-payment, representing approximately 6.84 percent of the total number of policies terminated for non-payment. Even though $5 may represent a large percentage of an enrollee's portion of the premium less APTC, we believe that triggering a grace period or terminating enrollment through the Exchange is too severe a consequence for non-payment of such limited dollar amounts.

We are concerned about situations in which an issuer would be willing to avoid termination of enrollment through the Exchange if the enrollee owed only small amounts of premium but are prevented from doing so by the lack of flexibility in the current regulation. In addition, many of the enrollees who enter a grace period because they owe de minimis amounts of premium are likely low or moderate-income enrollees and thus might be especially hurt by disruptions in coverage. We recognize that issuers have historically implemented various premium payment thresholds, and we believe there is value in providing flexibility to issuers regarding whether to adopt a fixed-dollar payment threshold and the amount of the threshold.

We thus propose to modify § 155.400(g) to allow issuers to adopt a fixed-dollar premium payment threshold of $5 or less, adjusted for inflation, under which they could provide additional flexibility to enrollees who fail to pay the full amount of their portion of premium owed. We propose to limit the fixed-dollar premium threshold to $5 or less because, unlike the current percentage-based threshold, a fixed-dollar threshold would allow enrollees, in some cases, to pay $0 in premium without the issuer triggering a grace period or terminating enrollment through the Exchange. Such a limit would ensure that enrollees who owe large amounts of premium do not remain enrolled in coverage through the Exchange and would serve to limit the number of times an enrollee may fail to pay premium and avoid triggering a grace period or termination of enrollment through the Exchange. We believe that a limit of $5 is sufficiently large to enable issuers to allow enrollees who owe *de minimis* amounts of premium to remain enrolled, while ensuring that enrollees do not accumulate excessive amounts of premium owed prior to triggering a grace period or termination of enrollment through the Exchange. We recognize that this amount might be lower than the threshold enrollees might be afforded under a percentage-based threshold. However, we also recognize that within a percentage-based threshold, the enrollee must pay a certain amount of their premium to avoid triggering a grace period or termination of enrollment through the Exchange, whereas with a fixed-dollar threshold, an enrollee may not have paid any other amount than the binder payment. Other factors such as the amount the enrollee has paid for their premium to date is not considered when applying the fixed-dollar payment threshold. We request comment on whether this is a reasonable limit for the fixed-dollar threshold, or whether an alternative amount (such as $10) would be more appropriate and in line with our goal of enabling enrollees who owe small amounts of premiums, while avoiding excessive accumulation of premium debt, to avoid triggering a grace period or termination of enrollment through the Exchange. If adopted, we would publish updates through subregulatory guidance to this $5 limit to adjust for inflation, using the National Health Expenditure Forecast published annually by CMS' Office of the Actuary.[191]

Issuers that adopt such a policy could permit enrollees who owe less than the specified amount of premium to avoid triggering a grace period and termination of enrollment through the Exchange. However, we propose to limit application of this threshold to premium payments made after coverage is effectuated, so that it could not apply to the binder payment. Issuers have the option under the current percentage threshold policy at § 155.400(g)(1) of applying a percentage-based threshold to the binder payment, but under that policy, enrollees are required to pay some amount of premium, even if it less than the total. By contrast, under a fixed-dollar premium payment threshold, enrollees could have their coverage effectuated without making any payment if their portion of the binder payment is under the threshold amount. Due to concerns about program integrity, we believe it is important to ensure that, when a binder payment is required, enrollees must always pay some amount of premium to effectuate coverage as an important signal that the coverage is desired by the enrollee. In addition, as under the current policy (81 FR 12272), any amount that is unpaid but within the reasonable premium payment threshold established by an issuer remains an amount owed by the enrollee and cannot be forgiven by the issuer. This remains true whether the premium payment threshold is utilized for any of the following payments: binder payments, regularly billed payments, or amounts owed by an enrollee while in a grace period.

[189] 2017 Payment Notice, 81 FR 12203, 12272.

[190] See CMS. (2023, July 12). *2023 Federally-facilitated Exchange (FFE) Enrollment Manual.* (Section 6.2, pp. 89–91). *https://www.cms.gov/files/document/ffe-enrollment-manual-2023–5cr-071323.pdf.*

[191] See CMS. (n.d.). *National health expenditure data—Projected. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected.*

To illustrate how a fixed-dollar premium threshold will work under this proposal, we provide the following example:

Example 1: During the annual Open Enrollment Period, a consumer selects a QHP with a total monthly premium amount of $300, and the consumer is determined eligible for $299 in APTC and elects to receive the entire amount. The consumer's enrollee-responsible portion of premium will thus be $1. The QHP issuer has adopted a fixed-dollar premium payment threshold policy under which it will not terminate enrollment of enrollees who owe $5 or less of the enrollee-responsible portion of premium. The issuer has set a binder payment deadline of January 30, and the consumer sends the binder payment of $1 ahead of the deadline and effectuates coverage effective January 1. Subsequently, the consumer does not make a payment for February, March, April, May, or June, and, as a result, the enrollee owes $5 in outstanding premiums. Because the issuer has adopted a $5 premium payment threshold, the issuer would not put the consumer into a grace period, since the total amount owed does not exceed $5. However, the issuer would not be permitted to write off the $5 owed, and if the consumer does not pay the premium for July in full, the issuer must put the consumer into a 3-month grace period since the total amount of premium owed would exceed the threshold set by the issuer. However, if within the grace period the consumer paid the full amount owed or a portion of the full amount owed that brings the amount owed under $5, the issuer could terminate the grace period without terminating enrollment through the Exchange.

Finally, under the current percentage-based threshold policy, the percentage is calculated based on the percentage paid of the enrollee's portion of the premium (that is, the total premium minus any APTC). We are considering whether to further amend § 155.400(g) to also permit issuers to set a reasonable threshold that is a percentage of the policy's total premium and not just the enrollee's portion of premium, thus allowing APTC paid on the consumer's behalf to count toward the threshold.

In the 2017 Payment Notice (81 FR 12271 through 12272), we established the option for issuers to adopt a premium payment threshold based on net premium owed by the enrollee. At that time, we did not consider establishing a threshold based on gross premium, nor have we done so since then. We now recognize that this option may provide issuers with an alternative method of keeping consumers enrolled in coverage that issuers may prefer, either because it is simpler to implement or because it is percentage-based and therefore more similar to the premium payment threshold that is currently allowed under § 155.400(g).

Establishing an option for issuers to adopt a percentage threshold based on gross premium owed by the enrollee with APTC counting toward the threshold would, in some cases, allow enrollees to remain enrolled in coverage or avoid triggering a grace period or termination of enrollment through the Exchange for owing small amounts of the enrollee-responsible portion of the premium. For example, an enrollee whose gross premium was $600, and was receiving $595 in APTC, could avoid triggering a grace period or termination of enrollment through the Exchange or termination of coverage even without paying the $5 enrollee-responsible portion of the premium if the issuer had adopted a 99 percent premium threshold based on gross premium because 99 percent of the gross premium would have been paid on the enrollee's behalf in the form of APTC. With the current 95 percent threshold based on net premium, by contrast, the enrollee would be required to pay at least $4.75 to avoid triggering a grace period or termination of enrollment through the Exchange. While historically we have not defined a specific threshold for the premium threshold based on net premium, we would implement a threshold for the premium threshold based on gross premium that is 99 percent or more of the gross premium. We believe the gross premium threshold should be higher than the net premium threshold to avoid the enrollee accumulating a much larger amount of premium debt, and to keep to a similar *de minimis* amount of premium owed as the net premium percentage-based and fixed-dollar thresholds allow. Because this threshold would also, in some circumstances, allow enrollees to temporarily avoid paying any premium, we would also propose to limit application of this threshold to premium payments made after coverage is effectuated, so that it could not apply to the binder payment (due to operational and program integrity concerns, as discussed earlier in this section).

A percentage threshold based on gross premium may be simpler to implement, since it is similar to the type of threshold issuers are already allowed to adopt. However, we recognize that there may also be drawbacks to this approach, including that enrollees could accumulate more than $5 in premium debt, which the enrollee would continue to owe even if coverage were eventually terminated due to non-payment of premiums. Based on our experience with the current, net premium-based payment threshold, we do not believe this would result in significant premium debts accumulated by enrollees, since we are limiting the gross percentage-based threshold to be 99 percent or more of the gross premium. We recognize that a gross premium amount higher than the average gross premium (which was $604.78 in February 2023)[192] might allow enrollees to accrue more than the $5 debt that could be accrued under the fixed-dollar threshold, but this is true under the existing net premium payment threshold as well. We also note that issuers are prohibited from attributing premiums owed to prior debts and not to binder payments, and thus issuers may not refuse to enroll enrollees in coverage based on failure to pay their binder payment by attributing binder payments to prior debts.

To illustrate how a premium threshold based on gross premium would work under this proposal, we provide the following example:

Example 2: During the annual Open Enrollment Period, a consumer selects a QHP with a total monthly premium amount of $500, and the consumer is determined eligible for $495 in APTC and elects to receive the entire amount. The consumer's enrollee-responsible portion of premium will thus be $5. The QHP issuer has adopted a percentage-based premium payment threshold policy under which it will not trigger a grace period or termination of enrollment through the Exchange for enrollees who pay at least 99 percent of gross premium (including payments of APTC made on the enrollee's behalf), which here would be $5. The issuer has set a binder payment deadline of January 30, and the consumer sends the binder payment of $5 ahead of the deadline and effectuates coverage effective January 1. Subsequently, the consumer pays $1 in February and owes $4 in past due premium; because the consumer's payment is within the 99 percent threshold established by the issuer, the issuer would not place the enrollee in a grace period. The following month, the consumer does not pay any premium, and now owes $9 in past due premium. Since the $9 now owed after application of the $495 APTC paid on the consumer's behalf for March represents more than 1 percent of the $500 gross premium, the issuer must put the consumer into a 3-month grace period starting March 1. The issuer would not be permitted to write off the $9 owed, and the consumer must pay all outstanding premium owed before the end of the grace period (May 31) to avoid exhaustion of the grace period and remain enrolled in coverage.

We seek comments on this proposal. Specifically, we request comment on whether a fixed-dollar threshold, as

[192] See CMS (2024) *Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average. https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf.*

proposed, or a percentage threshold based on gross premium, would better meet our goal of providing flexibility to issuers to allow enrollees to avoid triggering a grace period or termination of enrollment through the Exchange for owing small amounts of premium.

We also propose changing the premium payment threshold based on net premium owed by the enrollee from being a ''reasonable'' standard to a specifically defined threshold of 95% or higher of the net premium. We believe this would provide clarity for issuers and Exchanges.

We also propose limiting issuers to utilize one premium payment threshold, such that a fixed-dollar threshold cannot be adopted and utilized in tandem with a percentage-based policy, either net or gross. We believe that limiting this flexibility would allow issuers to choose and apply the threshold that works best for their payment operations but prevents complex situations that may arise from allowing multiple thresholds to be used simultaneously. We seek comment on whether we should allow issuers to adopt both a fixed-dollar and percentage-based threshold, and request commenters to consider the administrative feasibility of applying both thresholds, and how such a policy could be applied uniformly and consistently across enrollees.

6. General Eligibility Appeals Requirements (§ 155.505)

We propose revising § 155.505(b) to codify an option for application filers to file appeals on behalf of applicants and enrollees on the application filer's Exchange application.

The Exchanges on the Federal platform allow application filers as defined under § 155.20 to file applications on behalf of an applicant. However, the appeals regulation at § 155.505(b) states that only applicants and enrollees may submit appeal requests to the HHS appeals entity or a State Exchange appeals entity. Appeal requests submitted online to the HHS appeals entity are linked to a consumer's *HealthCare.gov* account, which is controlled by the application filer. Thus, an application filer who has authority to apply for coverage through *HealthCare.gov* on behalf of an applicant under § 155.20, does not have parallel authority under § 155.505(b) to appeal a contested eligibility determination on behalf of that applicant through the same *HealthCare.gov* account.

This limitation under § 155.505(b) puts a burden on consumers, as appeals filed by application filers who are neither an applicant or enrollee are considered invalid based on lack of standing, requiring either that the applicant or enrollee resubmit their appeal or that they designate the application filer as an authorized representative in writing. These extra steps not only add unnecessary complications for the applicant or enrollee, but also serve to delay an appeal resolution that may grant or restore QHP coverage and financial assistance.

This proposed change would allow application filers to file appeals through the HHS appeals entity or a State Exchange appeals entity on behalf of applicants and enrollees on their Exchange application, streamlining the appeals process and ensuring operational consistency throughout the application and appeals processes. We do not anticipate that this would impose any additional substantial burden on any Exchanges, including State Exchanges that operate their own platform, as this should not materially increase the number of appeals filed, or add complexity to appeals processes.

We seek comment on this proposal.

7. Certification Standards for QHPs (§ 155.1000)

We propose to amend § 155.1000 by adding a new paragraph (e) stating that an Exchange may deny certification of any health plan as a QHP that does not meet the general certification criteria at § 155.1000(c).

Section 1311(e)(1) of the ACA grants an Exchange the authority to certify a health plan as a QHP if the health plan meets the requirements for certification promulgated by the Secretary under section 1311(c)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State.[193] In the Exchange Establishment Rule (77 FR 18310, 18404 through 18405), we codified the responsibilities of an Exchange to certify QHPs at § 155.1000, and under § 155.1000(b), required Exchanges to only offer health plans which have in effect a certification issued or are recognized as health plans deemed certified for participation in an Exchange as a QHP. In that final rule, we also codified general certification criteria, consistent with sections 1311(e)(1)(A) and (B) of the ACA, at § 155.1000(c): an Exchange may certify a plan as a QHP if: (1) the health insurance issuer provides evidence during the certification process that it complies with the applicable minimum certification requirements outlined in subpart C, part 156 of our regulations; and (2) the Exchange determines that making the health plan available through the Exchange is in the interest of qualified individuals and qualified employers.[194]

However, an Exchange's authority to deny certification is not explicitly referenced in 45 CFR part 155. Several regulations, including §§ 155.1000(c) and 155.1090, can be read to imply, but do not explicitly state, that an Exchange may deny certification of a health plan that does not meet the requirements of § 155.1000(c). Despite this omission from our regulations, a plain reading of section 1311(e)(1) of the ACA makes clear that an Exchange, as the entity statutorily responsible for determining whether a plan meets the minimum QHP certification standards, has the implied authority to deny certification of plans that do not meet these standards. Any contrary read of section 1311(e)(1) of the ACA would mean that an Exchange does not have any statutory authority to take any action for plans that do not meet minimum certification standards, which is not a reasonable result.

We seek to revise our regulations so that they more fully and accurately reflect the discretion that Exchanges have to deny certification of any plan that does not meet the general certification criteria at § 155.1000(c). Accordingly, we propose to use the authorities under section 1311(c) of the ACA (which gives HHS the authority to establish criteria for the certification of health plans as QHPs), section 1311(d)(4)(A) (which provides that Exchanges shall implement procedures for the certification, recertification, and decertification of QHPs consistent with the guidelines HHS develops under section 1311(c)), and section 1321(a)(1)(B) (which provides HHS with broad rulemaking authority to issue regulations setting standards for meeting the requirements under title I of the ACA (which includes section 1311) for the establishment and operation of Exchanges and the offering of QHPs through the Exchanges) to add new paragraph (e) to § 155.1000 to formalize

[193] Section 1311(c)(1)(B) of the ACA and § 155.1000(c)(2) further provide that an Exchange may not exclude a health plan (i) on the basis that such plan is a fee-for-service plan, (ii) through the imposition of premium price controls, or (iii) on the basis that the plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

[194] In that rule, we outlined a number of non-exhaustive strategies an Exchange may employ to determine whether the offering of a health plan is in the interest of qualified individuals and qualified employers (77 FR 18406).

the implicit authority that an Exchange, including State Exchanges and SBE–FPs, may deny certification to any plan that does not meet the general certification criteria at § 155.1000(c). Under this proposal, an Exchange may deny certification if the issuer does not provide evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements (under § 155.1000(c)(1)), or if the Exchange determines that making the health plan available is not in the interest of the qualified individuals and qualified employers (under § 155.1000(c)(2)).

To be clear, we are not proposing to require Exchanges, including State Exchanges and SBE–FPs, to implement any specific procedures or processes for the denial of a QHP certification application. This proposal is not intended to amend the existing, implied authority of an Exchange to deny certification. This proposal is only intended to make that authority more explicit in our regulations, which will provide greater certainty to Exchanges, issuers, and consumers on an Exchange's role, which we expect will only improve the efficiency of the Exchanges.

We seek comment on this proposal.

8. Request for the Reconsideration of Denial of Certification Specific to the FFEs (§ 155.1090)

We propose to amend § 155.1090 to revise the standards for an issuer to request the reconsideration of denial of certification as a QHP specific to the FFEs.

Section 1311(e)(1) of the ACA grants an Exchange the authority to certify a health plan as a QHP if the health plan meets the requirements for certification promulgated by the Secretary under section 1311(c)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State.[195] In the 2018 Payment Notice (81 FR 94137), we finalized § 155.1090 to allow an issuer to request the reconsideration of a denial of certification of a plan as a QHP for sale through an FFE.

HHS, as operator of the FFEs, is responsible for ensuring that health plans offered through the FFEs meet all Federal requirements for certification as QHPs under § 155.1000(c). Starting with the 2014 plan year, HHS has certified numerous health plans as QHPs on the FFEs. During this time, HHS has also determined that a small number of applications submitted by issuers for the certification of health plans as QHPs on the FFEs did not meet minimum certification criteria under § 155.1000(c), and HHS denied certification to these plans. Some of these issuers submitted reconsideration requests to HHS under § 155.1090(a)(1). HHS ultimately sustained its denial determinations for these issuers' certification applications upon reconsideration review.

Based on our experience reviewing these certification application reconsideration requests, we believe that it would be appropriate to amend § 155.1090 to codify more structure for the FFEs' process for conducting a reconsideration of denial of certification. Accordingly, we propose to use the authorities under section 1311(c) of the ACA (which gives HHS the authority to establish criteria for the certification of health plans as QHPs), section 1311(d)(4)(A) (which provides that Exchanges shall implement procedures for the certification, recertification, and decertification of QHPs consistent with the guidelines HHS develops under section 1311(c)), and section 1321(a)(1)(B) (which provides HHS with broad rulemaking authority to issue regulations setting standards for meeting the requirements under title I of the ACA (which includes section 1311) for the establishment and operation of Exchanges and the offering of QHPs through the Exchanges) to require that an issuer's reconsideration request meet a specified burden of proof. Specifically, we propose revising § 155.1090(a)(2) to state that the burden is on an issuer that is denied certification to provide evidence that HHS' determination that the plan does not meet the certification criteria at § 155.1000(c) was in error.

As we stated in the Exchange Establishment Rule (76 FR 41891), offering only QHPs through an Exchange assures consumers that the coverage options presented through the Exchange meet certain minimum Federal standards. Given the voluntary nature of QHP certification, the FFEs utilize a process for QHP certification whereby the burden of proof is on issuers to provide sufficient evidence that they comply with those minimum Federal standards to obtain certification.[196] Consistent with this general approach towards QHP certification, we believe it is appropriate to propose formalizing that the burden of proof involved in a reconsideration request is also on issuers. Under this proposal, an issuer that is denied certification on an FFE would be responsible for submitting a request to HHS, as operator of the FFEs, for reconsideration of a denial determination.

We also propose to revise § 155.1090(a)(2) to require that, as part of a reconsideration request, an issuer would be required to submit clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error. We explained in the 2017 Payment Notice (81 FR 12289) that HHS expects to certify the vast majority of plans that meet the certification standards. To maximize this amount of time for health plans to prepare, submit, and revise QHP applications to the FFEs, HHS provides as much time as it can for issuers to demonstrate that they comply with the certification standards. The FFE's QHP certification timeline provides at least three opportunities for issuers to submit application materials to demonstrate that it meets minimum certification standards for a given plan year (four opportunities, if the issuer avails itself of an optional early bird submission). As such, by the time it issues a denial of certification, HHS will have typically already received substantial factual information from the issuer over the period of several months upon which it will have based its denial determination. It is unlikely that any additional evidence that the issuer would seek to provide upon reconsideration request that they had not already provided during the three or four rounds of application submissions would meaningfully weigh in favor of certification unless it clearly and convincingly establishes that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error.

Under this proposal, we would expect evidence to be clear and convincing that HHS' determination was in error if the issuer demonstrates that HHS clearly misunderstood or misinterpreted facts or data already provided by the issuer in previously submitted application materials (such as network adequacy calculation errors). We would not

[195] Section 1311(c)(1)(B) of the ACA and § 155.1000(c)(2) further provide that an Exchange may not exclude a health plan (i) on the basis that such plan is a fee-for-service plan, (ii) through the imposition of premium price controls, or (iii) on the basis that the plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

[196] See § 155.1000(c)(1): ''The health insurance issuer provides evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements outlined in subpart C of part 156, as applicable.''

expect evidence to be clear and convincing in this regard if it is substantially based on new information (such as the inclusion of new ECPs that the issuer did not include in previously submitted application materials) or is comprised of disputes of HHS' authority to ensure compliance with certification standards (such as a determination that making the plan available is not in the interest of the qualified individuals and qualified employers, under section 1311(e)(1)(B) of the ACA and § 155.1000(c)(2)) that would require HHS to perform de novo analysis before open enrollment.

Finally, we propose to revise the title of § 155.1090 to state, ''Request for the reconsideration of a denial of certification'' and the subtitle of § 155.1090(a) to state, ''Request for the reconsideration of a denial of certification specific to a Federally-facilitated Exchange.''

We seek comment on this proposal.

9. General Program Integrity and Oversight Requirements (§ 155.1200)

We currently collect certain information and data from State Exchanges and SBE–FPs under § 155.1200 to monitor their performance and compliance. Under our authority under section 1321(a)(1)((D) of the ACA to promulgate appropriate requirements related to Exchanges, we are proposing to also use this information and data to increase transparency into State Exchange operations and to promote program improvements.

Under § 155.1200, State Exchanges must report to HHS on certain Exchange-related activities and performance monitoring data. State Exchanges must also engage an independent qualified auditing entity which follows generally accepted government auditing standards (GAGAS) to annually compile a financial statement and conduct a financial audit and a programmatic audit.

To meet these requirements, under section 1313(a)(1) of the ACA, State Exchanges and SBE–FPs are required to submit a State Marketplace Annual Reporting Tool (SMART) to CMS, which CMS uses to monitor and evaluate State Exchange compliance with Exchange requirements under Title I of the ACA.[197] Through the SMART, State Exchanges and SBE–FPs attest to compliance with specific regulations, provide supporting documentation including, if applicable, a redetermination plan for the upcoming plan year, an oversight and monitoring plan with fraud, waste, and abuse policies and procedures, nondiscrimination policies and standards, and an operating budget with a financial statement. Additionally, the Exchanges submit the financial and programmatic audits with corrective action plans for any identified audit or findings. Following review, we provide State Exchanges and SBE–FPs with a SMART summary letter based on the observations and action items identified and monitor State Exchange completion of any open findings.

State Exchanges that operate their own eligibility and enrollment platform also report enrollment and Exchange activity data to CMS weekly during Open Enrollment and twice a year outside of Open Enrollment.[198] We publish Exchange Open Enrollment data annually.[199] We utilize the programmatic data received from State Exchanges to identify program risks and provide technical assistance to State Exchanges on corrective actions or strategies to mitigate risks, as well as to inform the development of new or updated policies as part of our annual rule-making processes to address known risks.

In the 2025 Payment Notice (89 FR 26218), we noted that in the interest of transparency, we are considering the development of new tools to provide further information to the public about the performance of Exchanges. We are now proposing that, in addition to collecting the information and data currently submitted to CMS by State Exchanges and SBE–FPs under § 155.1200 to monitor performance and compliance, we would use the information and data to increase transparency into State Exchange operations and to promote program improvements. We would value feedback on our proposed approaches to meeting this objective.

Specifically, we plan to publicly release the State Exchange and SBE–FP annual SMARTs and financial and programmatic audits in addition to any documentation of corrective actions or open findings. We believe that in addition to increasing the public's understanding of State Exchanges, the release of the SMARTs and related documents, including programmatic and financial audits, would help ensure that the SMART and State Exchange compliance activities are conducted in a more transparent manner. Our intention is to begin with publication of the Plan Year 2023 SMART (which was due from the State Exchanges and SBE–FPs to CMS on June 1, 2024, and are currently under compliance review) beginning Spring 2025.

We also intend to expand on current Open Enrollment data reporting by publishing, additional metrics on State Exchange operations and functionality that we currently collect from State Exchanges, but do not currently report to external audiences. This data includes State Exchange spending on outreach (including Navigators), eligibility and enrollment policies and processes, plan certification requirements, and operational performance data, including Open Enrollment call center metrics (call center volume, average wait time, average call abandonment rate) and website visits and visitors. We believe that increasing transparency would allow the public to better understand the performance of the Exchanges, and it is our intention that this public reporting of State Exchange operations and functionality would include public release of comparable metrics for the FFEs and SBE–FPs.

We are interested in comments as to what other Exchange metrics would be useful to disclose to the public.

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

1. Solicitation of Comments—Reducing the Risk That Issuer Insolvencies Pose to the Integrity of the Federally-Facilitated Exchanges

Several instances of issuer insolvencies (each involving multi-State parent organizations with several subsidiaries) have in recent years destabilized certain State markets and caused significant disruption to consumers, including in the applicable Exchanges. The disruptive nature of these incidents prompted State Departments of Insurance (DOIs), trade organizations, and issuers to request that we intervene to restabilize affected markets and employ additional measures to reduce the risk of similar scenarios occurring in subsequent years. In response to this feedback, we are soliciting comments on methods that HHS, as operator of the FFEs, could potentially employ, in partnership with State regulators, to reduce the risk that

[197] OMB. *State-based Marketplace Annual Reporting Tool (SMART).* OMB control number: 0938–1244. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/smart_2017_5.pdf.*

[198] OMB control number: 0938–1119.

[199] See, for example, CMS. (2024, March 22). *2024 Marketplace Open Enrollment Period Public Use Files. https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2024-marketplace-open-enrollment-period-public-use-files.*

issuer insolvencies pose to the integrity of the FFEs.

One example of a potential approach we are considering adopting, and therefore solicit comment on, could be to increase our coordination with State DOIs, individually and collectively in the case of multi-State issuers, and the National Association of Insurance Commissioners (NAIC). Under this approach, we could review QHP applications in FFE States to identify issuers that are at risk of experiencing solvency-related difficulties, both at the time of an issuer's application for QHP certification and on a rolling basis throughout the plan year. To assess issuer solvency, we could examine well-understood and industry-standard financial measures, such as the risk-based capital ratio and quick ratio, in partnership with State regulators.

The risk-based capital ratio is an industry-standard regulatory method used to determine the minimum amount of capital an issuer must maintain to cover its risk. The risk-based capital ratio an issuer must maintain (in accordance with State licensure requirements) is based on the inherent level of risk associated with its financial assets, insurance products, and business operations. The risk-based capital ratio is defined as the ratio of an issuer's total adjusted capital to its authorized control level risk-based capital. Total adjusted capital is typically cash or liquid assets being held or obtained for expenditures. Authorized control level risk-based capital, also referred to as risk-weighted assets, is the denominator in the risk-based capital ratio. Authorized control level risk-based capital is used to determine the minimum amount of capital an issuer must hold in relation to the risk profile of its activities and other assets.[200]

A low risk-based capital ratio may indicate that an issuer is insufficiently capitalized and therefore may be unable to pay claims and risk adjustment charges in a longer time horizon. Thus, monitoring issuers' risk-based capital ratios enables regulators to identify potentially insufficiently capitalized issuers, which could facilitate necessary regulatory intervention to ensure enrollees receive benefits without relying on a guaranty association or taxpayer funds. In the context of the Exchanges, such regulatory intervention could include implementing plan suppressions, enrollment caps, denying QHP certification, or decertifying existing QHPs.

While the risk-based capital ratio provides a measure of an issuer's overall long-term financial viability, it does not so readily indicate whether an issuer is able to pay claims or risk adjustment charges in the more immediate term by quickly liquidating its assets. For example, an issuer could have a risk-based capital ratio indicating a sufficient degree of capitalization but may not be able to quickly liquidate its assets to cover its immediate liabilities, either in the form of claims or risk adjustment payments.

As such, we are interested in comments on whether we should consider also utilizing a second industry-standard measure of financial instability, the quick ratio, which is a type of liquidity ratio, to assess issuer solvency. The quick ratio measures an issuer's ability to use its near-cash or ''quick'' assets to extinguish or retire its current liabilities immediately. The quick ratio is defined as the ratio between quickly available or liquid assets and current liabilities.[201] Quick assets are current assets that can presumably be quickly converted to cash at close to their book values. Possessing sufficient quick assets ensures issuers are able to timely cover all claims in a more immediate timeframe.

The quick ratio is a more conservative estimate of how liquid a company is compared to other calculations that include potentially illiquid assets, such as the risk-based capital ratio. In particular, the quick ratio addresses an issuer's ability to pay outstanding debts. This financial metric alone does not provide any indication about a company's future cash flow activity. However, the utilization of the quick ratio, in conjunction with the risk-based capital ratio, could potentially facilitate the identification of issuers with potential financial viability concerns that may pose risk to the integrity of the FFEs.

Altogether, monitoring issuers' risk-based capital ratios could facilitate the assessment of an issuer's longer-term prospects for financial viability, while monitoring issuers' quick ratios could facilitate the assessment of issuers' more immediate term prospects for financial viability. Together, the utilization of these two complementary measures could potentially provide a more holistic view of issuers' financial viability and help HHS, as operator of the FFEs, in partnership with applicable State DOIs, take the action necessary to ensure the integrity of the FFEs (such as by suppressing QHPs under § 156.815, instituting enrollment caps—which have been previously operationalized by implementing QHP suppressions under § 156.815(b)(5) based on the guaranteed availability exceptions at § 147.104(c) and (d), denying QHP certification applications under § 155.1000(c), or decertifying QHPs under § 156.810).

Under this potential approach, HHS, in partnership with State regulators, could assess an issuer's financial stability based on its risk-based capital ratio and its quick ratio using data that is included in the statutory annual and quarterly financial statements that issuers are already required to file with the NAIC. Since these materials are already available to HHS, this approach would not require issuers to prepare and submit additional materials to HHS, which would minimize burden on QHP issuers.

In addition to monitoring issuers' risk-based capital ratios and quick ratios to identify issuers at risk of experiencing solvency-related difficulties, HHS could work in partnership with applicable State regulators to identify issuers that are experiencing levels of enrollment growth that risk exceeding their capitalization rates, which has historically tended to occur in large part due to the relative premium position of issuers' newly-offered plans (specifically, having the lowest-cost bronze or silver plan in the county).

Issuers experiencing enrollment growth disproportionately comprised of comparatively low-risk enrollees that exceeds their capitalization rates has been a primary contributing factor in each of the recent instances of issuer insolvencies. In particular, in these instances of issuer insolvencies, insufficiently capitalized issuers underpriced their QHPs, which attracted a high number of relatively low-risk enrollees. These issuers subsequently accrued significantly higher-than-anticipated risk adjustment charges due to the relatively low risk profiles of their enrollees, which in turn led to these issuers being unable to timely pay risk adjustment charges in full.

Upon identifying issuers with insufficient risk-based capital and quick ratios, and/or issuers with enrollment growth that risks exceeding their capitalization rates, HHS could engage applicable State regulators—including State regulators in the affected States, regulators of those issuers in their States of domicile, and regulators of affiliated

[200] National Association of Insurance Commissioners. (2024, Jan. 1). *Risk-Based Capital. https://content.naic.org/cipr-topics/risk-based-capital.*

[201] Corporate Finance Institute. (n.d.) *Quick Ratio. https://corporatefinanceinstitute.com/resources/accounting/quick-ratio-definition/.*

entities within the same parent organization domiciled in other States. HHS and those State regulators could then discuss the advisability of having these plans certified to be offered on their respective Exchanges. Discussions with State regulators could include whether those States should request that HHS invoke the exceptions to guaranteed availability for financial capacity under § 147.104(d), and whether States should request that HHS institute a temporary enrollment cap if an issuer demonstrates an insufficient risk-based capital ratio and/or quick ratio, or if an issuer experiences enrollment growth that risks exceeding its capitalization rate.

Under this potential approach, we could monitor issuers offering QHPs through the FFEs—but not issuers only offering QHPs through State Exchanges or SBE–FPs. This is because we believe that State Exchanges (including SBE–FPs) are best positioned to understand both the nuances of their respective markets and the specific needs of qualified individuals enrolling in QHPs. We also believe that States that have invested the necessary time and resources to establish State Exchanges have done so to implement policies that differ from those on the FFEs, and we do not wish to impede these efforts, so long as they comply with existing legal requirements. However, we believe that HHS can serve a useful role in identifying broader risks that span multiple markets by convening States that regulate multi-State issuers.

State regulators are the primary regulators of licensure requirements, including solvency. Indeed, we strongly believe that States are best positioned to exercise these responsibilities as a general matter. Since HHS, as the operator of the FFEs in many States and as the operator of risk adjustment in all States, has a more complete view of multi-State issuers, and, in FFE States, the ability to wield Exchange-specific tools (such as plan suppressions, enrollment caps, denial of QHP certification applications, and the decertification of existing QHPs), we believe HHS can serve a useful role in promoting thoughtful discussions with and among State regulators around the advisability of certifying plans where there may be concerns around capitalization and enrollment growth that risks exceeding capitalization rates. Regardless, we underscore that nothing in this or any other potential approach we are considering would preempt any State's licensing requirements with regard to solvency or financial matters.

We solicit comments on this and other potential approaches for reducing the risk that issuer insolvencies pose to the integrity of the FFEs.

2. FFE and SBE–FP User Fee Rates for the 2026 Benefit Year (§ 156.50)

For the 2026 benefit year, we propose an FFE user fee rate of 2.5 percent of total monthly premiums and an SBE–FP user fee rate of 2.0 percent of total monthly premiums. These significant increases in the FFE and SBE–FP user fee rates would be necessary if Congress does not act to extend enhanced PTC subsidies [202] into 2026. In the absence of Congressional action, we project large decreases in enrollment for 2026, requiring us to reverse the reductions in the FFE and SBE–FP user fee rates that were made possible by record-setting enrollment in recent years.

However, Congressional action that extends the enhanced PTC subsidies under the IRA through the 2026 benefit year, prior to issuer rate-setting deadlines for the 2026 benefit year, would lead us to revise our enrollment projections and modify the FFE and SBE–FP user fee rates to rates closer to FFE and SBE–FP user fee rates for 2025 than the proposed rates. Specifically, if the enhanced PTC subsidies as currently enacted [203] or at a higher level are extended through the 2026 benefit year by March 31, 2025, we propose a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE–FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule. These ranges are based in part on projected enrollment during the 2025 open enrollment period. HHS will have a better understanding of the projected open enrollment numbers to finalize a single FFE and SBE–FP user fee rate within those ranges in the final rule (as more data about the 2025 open enrollment period will be available for calculating a single FFE and SBE–FP user fee rate for the final rule). In finalizing a single FFE and SBE–FP user fee rate within the proposed range, we would also consider any changes to our premium estimates or budget based on the most recently available data.

HHS also notes that this same dynamic related to lower enrollment is present across numerous calculations HHS makes associated with operation of the Exchange, outside the context of this proposed rule. For example, a reduction in enhanced PTC subsidies may considerably impact pass-through funding to States for programs established under Section 1332 waivers. Similarly, the expiration of enhanced PTC subsidies may affect BHP States' ability to implement, sustain, and expand their BHP programs. Lastly, we note that increased enrollment due to enhanced PTC subsidies has increased overall projected enrollment. In the absence of Congressional action to extend enhanced PTC subsidies, those calculations and payments will assume lower enrollment and lower APTC and PTC levels.

We are proposing March 31, 2025 as the date by which enhanced PTC subsidies must be extended in order for HHS to apply the alternative FFE and SBE user rates, because we anticipate this date as the latest date we could select that would still provide issuers the opportunity to take enactment of the law into account in setting rates for the 2026 benefit year and for HHS or States, as applicable, to timely review and approve those rates. However, we seek comment on whether March 31, 2025 provides sufficient time and whether we should select an earlier or later date.

Section 1311(d)(5)(A) of the ACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the ACA directs HHS to operate an Exchange within the State. Accordingly, in § 156.50(c), we state that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP. OMB Circular A–25 established Federal policy regarding user fees and what the fees can be used for.[204] OMB Circular A–25 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.

a. FFE User Fee Rates for the 2026 Benefit Year

Section 156.50(c)(1) provides that, to support the functions of FFEs, an issuer

[202] ARP, Public Law 117–2 (2021). These enhanced subsidies were extended under the IRA, Public Law 117–169 (2022) and are scheduled to expire after the 2025 calendar year.

[203] Ibid.

[204] See OMB. (n.d.) Circular No. A–25 Revised. *https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.*

offering a plan through an FFE must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE. As in benefit years 2014 through 2025, issuers seeking to participate in an FFE in the 2026 benefit year will receive two special benefits not available to issuers offering plans in State Exchanges: (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 2026 benefit year, issuers participating in an FFE will receive special benefits from the following Federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Activities performed by the Federal government that do not provide issuers participating in an FFE with a special benefit are not covered by the FFE user fee.

The proposed user fee rate reflects our estimates for the 2026 benefit year of costs for operating the FFEs, premiums, enrollment, and transitions in Exchange models from the FFE and SBE–FP models to either the SBE–FP or State Exchange models. The total enrollment in Exchanges in States anticipated to transition from operating an SBE–FP to a State Exchange model represents premiums for which we will no longer collect user fees, and the total enrollment in Exchanges in States anticipated to transition from an FFE to an SBE–FP model represents premiums for which we will assess user fees at the lower SBE–FP rate. Thus, these anticipated transitions impact our total projected collections and may affect the FFE and SBE–FP user fee rates and are considered as part of our calculation of our proposed user fee rates.

To develop the proposed 2026 benefit year FFE user fee rates, we considered a range of costs, premiums, and enrollment projections.[205] For the proposed 2026 benefit year user fee rates, we estimated that contract and labor costs would increase from the 2025 benefit year. Particularly, we have experienced increases in costs related to regulation of agents and brokers, consumer outreach and education, eligibility determinations, enrollment processes, and certification processes for QHPs.

We took several factors into consideration in choosing which premium and enrollment projections would inform the proposed 2026 FFE user fee rates. First, for our estimated premium trend rate projections, we found based on our analysis of historical premium trend data that our actual average premium trend rate was lower than we had estimated in prior benefit years and therefore, for our projected 2026 benefit year user fee rates, we decreased our estimated premium trend rate projections. This change serves to better align with our historical premium trend experience, and to reflect that the total monthly premiums to which the proposed FFE and SBE–FP user fee rates would be applied are likely to be lower than previously expected.

For the 2021 through 2025 benefit years, we projected increased enrollment in the individual non-catastrophic market risk pool in most States, due to the enhanced PTC subsidies provided for in the ARP[206] [207] and the extension of the PTC subsidies through the 2025 benefit year under section 12001 of the IRA.[208] Our 2026 enrollment estimates account for the projected transitions of States from FFEs or SBE–FPs to State Exchanges, the enrollment impacts of section 1332 waivers, and transitioning Medicaid Expansion States. We also carefully considered the impact of the expiration of the enhanced PTC subsidies on 2026 benefit year Exchange enrollment in the individual market.

We believe that the 2026 benefit year is uniquely uncertain due to the potential significant changes in enrollment expected if the enhanced PTC subsidies expire at the end of the 2025 benefit year under current law. We understand that many interested parties[209] have expressed interest in permanently extending the enhanced PTC subsidies established in section 9661 of the ARP and extended in section 12001 of the IRA beyond the 2025 benefit year. We recognize that the expiration of the subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and their expiration will have a ripple impact across the ACA markets.

For example, a reduction in enhanced PTC subsidies may considerably impact pass-through funding to States for programs established under Section 1332 waivers. In 2021, when the enhanced PTC subsidies first took effect, HHS and the Department of the Treasury awarded over $510 million in additional pass-through funding to 14 States in light of the enhanced subsidies through the ARP.[210] The expiration of the enhanced PTC subsidies would lead to a reduction in pass-through funding, which could require States to either allocate additional State funding to reinsurance programs or decrease the size of those programs.[211] This could potentially leave States with less State funding to pursue innovative State strategies to further improve affordability or lead to higher premiums. A majority of Section 1332 waiver programs are State-based reinsurance programs.[212] State-based reinsurance programs aim to reduce

[205] We considered the most recent projections from the Congressional Budget Office and, as we have in prior rulemakings, our own internal data. See, for example, 88 FR 25845; see also, Congressional Budget Office. (2024, June 18). *Health Insurance Coverage for the US Population, 2024 to 2034. https://www.cbo.gov/system/files/2024-06/60040-Health.pdf.*

[206] ARP, Public Law 117–2 (2021).

[207] CMS. (2023). *Summary Report on Permanent Risk Adjustment Transfers for the 2022 Benefit Year.* (p. 8). *https://www.cms.gov/files/document/summary-report-permanent-risk-adjustment-transfers-2022-benefit-year.pdf.*

[208] Inflation Reduction Act, Public Law 1217–169 (2022).

[209] For example, permanent extension of enhanced PTC subsidies is discussed in the President's 2025 Fiscal Year Budget (see *https://www.whitehouse.gov/wp-content/uploads/2024/03/budget_fy2025.pdf*) and the extension of enhanced PTC subsidies has also been addressed by the National Association of Insurance Commissioners in a letter to the U.S. Senate Committee on Finance and the U.S. House of Representatives Committee on Ways and Means (see *https://content.naic.org/sites/default/files/enhanced-subsidies-hill-letter-2024-final-july-2024.pdf*).

[210] CMS. (2021, Sept. 7). *American Rescue Plan Provides States Additional Funding to Lower Health Coverage Costs, Increase Affordability for Americans. https://www.cms.gov/newsroom/press-releases/american-rescue-plan-provides-states-additional-funding-lower-health-coverage-costs-increase.*

[211] An extension of the enhanced PTC subsidies' schedule has previously been projected to increase net Federal spending by about $18.4 billion in 2026. See OMB. (2024, March). *Budget of the U.S. Government Fiscal Year 2025.* Table S–6 (p. 143). *https://www.whitehouse.gov/wp-content/uploads/2024/03/budget_fy2025.pdf.* To the extent that a State's 1332 waiver reduces premiums or waives PTC, its 2026 pass-through funding would be higher by a portion of this amount.

[212] Twenty States have been granted State Innovation Waivers under Section 1332 of the ACA. Of these 20 States, 17 have reinsurance programs. The section 1332 website includes approved waivers here: *https://www.cms.gov/marketplace/states/section-1332-state-innovation-waivers.* Reinsurance programs can also be found here: *https://www.cms.gov/files/document/cciio-data-brief-042024-508-final.pdf.*

premiums for enrollees in the States' individual markets,[213] as well as reduce uncertainty in the range of premium increases.[214] A reduction in the amount of Federal pass-through funding for those programs resulting from the loss of enhanced PTC subsidies would likely have the inverse impact of putting upward pressure on premiums, making premiums higher compared to premiums without the enhanced PTC subsidies. This premium increase could result in lower enrollment and create significant uncertainty about the final combined impact of premium and enrollment changes on FFE and SBE–FP user fees, or it could result in a potentially higher user fee in order to maintain a similar level of user fee funding collections.

Furthermore, the expiration of enhanced PTC subsidies would impact funding available for States to operate BHP programs that enable enrollees that would otherwise be PTC-eligible to purchase healthcare coverage. This includes individuals under age 65 with household incomes between 133 percent and 200 percent of the FPL who are not otherwise eligible for Medicaid, CHIP, or other minimum essential coverage, or individuals whose income is equal to or below 133 percent of FPL but are lawfully present non-citizens ineligible for Medicaid, not otherwise eligible for minimum essential coverage. Expiration of enhanced PTC subsidies may affect BHP States' ability to implement, sustain, and expand their BHP programs, thereby impacting enrollment in these plans.

We also know that the enhanced PTC subsidies have resulted in major enrollment gains in the ACA markets over the last few years.[215] This is because ACA markets currently consist of additional enrollees who may not have selected plans previously during open enrollment, namely individuals newly eligible to receive tax credits.[216] Increased enrollment due to enhanced PTC subsidies has increased projected enrollment in our FFE and SBE–FP user fee calculations and has contributed to our ability to lower user fee rates over the past few years.

If enhanced PTC subsidies expire, we project that the total enrollment through FFEs and SBE–FPs would decrease at a similar rate as the Congressional Budget Office projections.[217] In turn, we anticipate that issuers would likely rate for the uncertainty associated with the expected decreased enrollment in the risk pool and increase premiums, potentially resulting in a decline in issuer participation within ACA markets in the long-term.

Lastly, we note that the expiration of enhanced PTC subsidies is not expected to decrease our FFE and SBE–FP budget estimates for operating the FFEs and SBE–FPs for the 2026 benefit year. This is because, while certain cost estimates would be expected to decrease with the expiration of enhanced PTC subsidies, such as printing and mailing of educational materials to enrollees and QHP certification, other costs and labor estimates would be expected to increase, such as the rate of eligibility appeal cases and inquiries to CMS Agent/Broker Marketplace Help Desks and Call Centers.

Despite the very high level of uncertainty discussed above, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the operations of the FFEs. After considering the range of costs, premiums, and enrollment projections, and considering how enhanced PTC subsidies could have a notable impact on our FFE and SBE–FP user fee rates, we propose a 2026 user fee rate that will ensure adequate funding for FFE operations. The proposed 2026 benefit year FFE user fee rate, which is 2.5 percent of total monthly premiums, is greater than the 2025 benefit year fee rate of 1.5 percent of total monthly premiums. Based on our estimates, this proposed user fee rate would allow us to have sufficient funding available to fully fund user-fee-eligible FFE activities. We note that if any events occurring between this proposed rule and the final rule significantly change our estimated costs to operate the FFEs or the Federal platform, or our projections of premiums or enrollment, we may finalize FFE and SBE–FP user fee rates that differ from these proposed rates to reflect those changes.

We seek comment on the proposed 2026 benefit year FFE user fee rate and the alternative proposed 2026 benefit year FFE user fee rate range (with this range to be set at a single rate in the final rule) if the current or a higher level of enhanced PTC subsidies are extended through the 2026 benefit year by March 31, 2025, including whether March 31, 2025 provides issuers sufficient time to request rates and for States to review and approve rate requests.

b. SBE–FP User Fee Rates for the 2026 Benefit Year

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 and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions and enhance efficiency and coordination between State and Federal programs. The benefits provided to issuers in SBE–FPs by the Federal government include use of the FFE information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the ACA, and QHP enrollment functions under 45 CFR part 155, subpart E. The user fee rate for SBE–FPs is calculated based on the proportion of total FFE costs associated with Federal activities that provide SBE–FP issuers with special benefits, including costs that are associated with the FFE information technology infrastructure, the consumer call center

[213] Overall, from PYs 2018 to 2023, States implementing Section 1332 State-based reinsurance programs for the individual market have seen statewide average SLCSP premium reductions ranging from 3.75 percent to 41.17 percent, compared to premiums absent the waiver. See *https://www.cms.gov/files/document/cciio-data-brief-042024-508-final.pdf.*

[214] Premium growth under reinsurance programs is slower and more stable, and therefore more predictable, than before reinsurance program implementation. See *https://www.cms.gov/files/document/1332-evaluation-oregon-2021.pdf, https://www.cms.gov/files/document/1332-evaluation-minnesota-2021.pdf,* and *https://www.cms.gov/files/document/1332-evaluation-alaska-2021.pdf.*

[215] See *https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf.*

[216] From 2022 to 2024, Exchange plan selection during open enrollment for individuals with incomes ≤200% of FPL increased by ~77%. For individuals with incomes of >200% of FPL and ≤400% of FPL, enrollment increased by ~15%. For individuals with incomes above 400% of FPL, enrollment increased by ~36.7%. Prior to the IRA and ARP, individuals with incomes above 400% of FPL were ineligible for the premium tax credit. Data sources: 2022 Marketplace Open Enrollment Period Public Use Files (*https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2022-marketplace-open-enrollment-period-public-use-files*) and 2024 Marketplace Open Enrollment Period Public Use Files (*https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2024-marketplace-open-enrollment-period-public-use-files*).

[217] According to Congressional Budget Office projections, Exchange enrollment will peak in 2025 and decline significantly by 2027 due to the expiration of enhanced PTC subsidies in 2025. See Congressional Budget Office and Joint Committee on Taxation projections of net Federal subsidies for health insurance (2023 through 2034): *https://www.cbo.gov/system/files/2024-06/51298-2024-06-healthinsurance.pdf.*

infrastructure, and eligibility and enrollment services.

To calculate the proposed SBE–FP rates for the 2026 benefit year, we used the same assumptions related to contract costs, enrollment, and premiums as we used for the proposed FFE user fee rates. As we explained previously in this section, the user fee rate for SBE–FPs is calculated based on the proportion of the total FFE costs associated with Federal activities that provide SBE–FP issuers with special benefits, which we continue to estimate to be approximately 80 percent of total FFE costs. These FFE costs associated with Federal activities that provide SBE–FP issuers with special benefits include the costs associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services.

Based on this methodology, the proposed 2026 benefit year SBE–FP user fee rate of 2.0 percent of total monthly premiums is greater than the user fee rate of 1.2 percent of total monthly premiums that we established for the 2025 benefit year. The proposed user fee rate for SBE–FP issuers for the 2026 benefit year also includes assumptions about States transitioning from either the FFE model to an SBE–FP, or from an SBE–FP to a State Exchange for the 2026 benefit year, which impacts the SBE–FP enrollment projections.

As discussed in detail above, we believe that the 2026 benefit year is uniquely different due to the potential significant changes to our projections if enhanced PTC subsidies expire at the end of the 2025 benefit year as currently expected. Despite this uncertainty, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the Federal platform operations for the SBE–FPs. For these reasons, we also propose an alternative SBE–FP user fee range between 1.4 percent and 1.8 percent of total monthly premiums if current or a higher level of enhanced PTC subsidies are extended through the 2026 benefit year by March 31, 2025, to be set at a single rate in the final rule.

We seek comment on the proposed 2026 benefit year SBE–FP user fee rate and the alternative proposed 2026 benefit year SBE–FP user fee rate range (with this range to be set at a single rate in the final rule) if the enhanced PTC subsidies are extended through the 2026 benefit year by March 31, 2025.

3. Silver Loading (§ 156.80)

Section 1402 of the ACA requires issuers to provide CSRs to help make health care more affordable for eligible low- and moderate-income consumers who enroll in silver level QHPs offered through the individual market Exchanges, as well as eligible American Indian (AI)/Alaska Native (AN) consumers who enroll in QHPs at any metal level. Section 1402 further states that HHS will reimburse issuers for the cost of providing CSRs. Until October 2017, the Federal government relied on the permanent appropriation at 31 U.S.C. 1324 as the source of funds for Federal CSR payments to issuers. However, on October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury with a legal opinion indicating that the permanent appropriation at 31 U.S.C. 1324 cannot be used to fund CSR payments to issuers.[218] In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides an appropriation.

In response to the termination of CSR payments to issuers, State DOIs generally permitted or instructed their issuers to increase premiums only, or primarily, on silver-level QHPs, to compensate for the cost of offering CSRs, since the vast majority of eligible enrollees receiving CSRs are enrolled in silver plans. This rating practice is sometimes referred to as ''silver loading'' or ''actuarial loading.'' Our regulations permit certain plan-level adjustments to the index rate on which premiums are based that are actuarially justified pursuant to the single risk pool requirements at § 156.80, and many States, which are the traditional regulators of insurance and rating practices, have provided issuers with pricing guidance specific to unpaid CSRs. For enrollees in silver plans who receive PTCs, the increase in PTCs corresponding to the higher premium rates generally fully offsets the higher premiums that they would otherwise experience because of silver loading.

In the January 24, 2019 **Federal Register** (84 FR 283), we sought comments on whether and how we might address the practice of silver loading through rulemaking, in the absence of Congressional action. All commenters recognized silver loading as an appropriate way to maintain consumer affordability and participation. In keeping with States' longstanding role as regulators of insurance premium setting, the majority of commenters urged us to continue to allow States to determine how to implement CSR loading. Some commenters expressed opposition to the practice of ''broad loading,'' in which issuers increase premiums on all plans (on- and off-Exchange) to mitigate the lack of CSR reimbursement. Those commenters stated that increasing premiums for all plans would force all unsubsidized consumers to pay higher premiums and would decrease APTC amounts. Commenters noted the reduction in financial assistance and large premium swings from year to year would cause consumer confusion and instability in the Exchanges, and such market disruption may lead to issuers leaving the Exchanges.

Since the cessation of CSR payments in 2017, States and issuers have asked us to clarify how the single risk pool rules at § 156.80 apply to actuarial loading. In guidance published in 2018, we stated that ''[a] plan-level variation for the actuarial value and cost-sharing design of a plan is permitted under § 156.80(d)(2)(i). A health insurance issuer that offers a QHP may vary premium rates for the QHP based on the impact of the loss of anticipated Federal funding for CSR payments.'' [219] In light of the continued absence of Congressional action to fund CSRs and given States' longstanding role as the primary regulators of insurance, we have consistently stated that the statute permits States' rating practices for silver loading or broad-loading, as long as the resulting rate adjustments are reasonable and actuarially justifiable pursuant to § 156.80.

Since we continue to receive questions about permissible actuarial loading practices, we affirm that silver-loading and broad-loading practices to increase premiums to offset amounts of unpaid CSRs that are permitted by State regulators are permissible under Federal law to the extent that they are reasonable and actuarially justified. We have long implemented section 1312(c) of the ACA by permitting issuers to vary premium rates for a particular plan from the market-wide adjusted index rate based on a limited set of actuarially justified plan-specific factors, including the actuarial value and cost-sharing design of the plan. For example, reasonable and actuarially justified silver loading practices reflect such a

[218] Sessions, J. (2017, Oct. 11). *Legal Opinion Re: Payments to Issuers for Cost Sharing Reductions (CSRs).* Department of Justice's Office of Attorney General. *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.*

[219] CMS. (2018, Aug. 3). *Center for Consumer Information & Insurance Oversight, Insurance Standards Bulletin Series—Information, Offering of plans that are not QHPs without CSR ''loading,'' https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Offering-plans-not-QHPs-without-CSR-loading.pdf.*

permissible variance because they relate to the actuarial value and cost-sharing design of silver-level plans, which are currently required to provide CSRs without reimbursement. We are considering codifying this policy by amending § 156.80(d)(2)(i) to clarify that the plan-specific factors by which issuers adjust the market-wide index rate include adjustments that reflect the costs associated with providing CSRs to the eligible enrollee population, to the extent that such adjustments are reasonable and actuarially justified. We seek comment on whether and how to codify this policy at § 156.80.

4. Publication of the 2026 Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage in Guidance (§ 156.130(e))

As established in part 2 of the 2022 Payment Notice (86 FR 24238), for benefit years in which we are not making changes to the methodology to calculate the premium adjustment percentage, the required contribution percentage, and maximum annual limitations on cost sharing and reduced maximum annual limitation on cost sharing, we will publish these parameters in guidance annually starting with the 2023 benefit year. Therefore, because we are not proposing to change the methodology for calculating these parameters for the 2026 benefit year, these parameters are not included in this rulemaking, and we intend to publish these parameters in guidance no later than December 31, 2024.

5. AV Calculation for Determining Level of Coverage (§ 156.135)

We intend to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator.

Section 2707(a) of the PHS Act and section 1302 of the ACA direct issuers of non-grandfathered individual and small group health insurance coverage, including QHPs, to ensure that plans meet a level of coverage, or metal tier, specified in section 1302(d)(1) of the ACA. Each level of coverage corresponds to an AV calculated based on the cost-sharing features of the plan. On February 25, 2013, HHS published the EHB Rule (78 FR 12834), implementing section 1302(d) of the ACA, which requires at subsection (d)(2)(A) that, to determine the level of coverage for a given metal tier, the calculation of AV be based upon the provision of EHB to a standard population. Section 156.135(a), as finalized in the EHB Rule, provides that an issuer must use the AV Calculator developed and made available by HHS for the given benefit year to calculate the AV of a health plan, subject to the exception in paragraph (b).

In the 2015 Payment Notice (79 FR 13744), we established at § 156.135(g) provisions for updating the AV Calculator in future plan years. We stated in the preamble of the 2015 Payment Notice that we intend to release a draft version of the AV Calculator and AV Calculator Methodology through guidance for public comment each plan year before releasing the final version. In that same rule, we noted that interested parties could submit feedback on changes to the AV Calculator, and that we would consult as needed with the American Academy of Actuaries and the National Association of Insurance Commissioners on changes to the AV Calculator.

In the 2017 Payment Notice (81 FR 12204), we reiterated this approach and amended § 156.135(g) to allow for additional flexibility in our approach and options for updating the AV Calculator each year, which include trend factor updates, algorithms changes, user interface changes, updates to the claims data and demographic distribution being used in the AV Calculator, and an update to the AV Calculator's annual limitation on cost sharing. We also stated that we intend to release the final AV Calculator for a respective plan year no later than the end of the first quarter of the preceding plan year.

Since this time, we have largely fulfilled this intention. However, we have received feedback that HHS should strive to release the final version of the AV Calculator even sooner, in anticipation of State filing deadlines. SBE–FPs have also provided feedback explaining that they could benefit from an earlier release of the final version of the AV Calculator to design standardized plan options that satisfy the AV de minimis ranges. We believe these requests are reasonable and that we can accommodate them in most years when there are no material changes between the draft and final versions of an AV Calculator for a respective plan year.

Therefore, we intend to revise the current method whereby HHS releases a draft version of the AV Calculator for a respective plan year through guidance for public comment and then releases the final version of the AV Calculator for that plan year no later than the end of the first quarter of the preceding plan year after considering any comments received. We intend to only release the single, final version of the AV Calculator for a respective plan year. Under this approach, we would still solicit public comments on the AV Calculator for a plan year generally, but we would only plan to incorporate this feedback into the development and release of the following plan year's AV Calculator, rather than to specifically inform the potential revision of the final version of the upcoming plan year's AV Calculator. This approach would allow HHS to release the final AV Calculator sooner. We anticipate that issuers would have the final version of the AV Calculator 3 to 6 months sooner than the end of the first quarter of the preceding plan year.

This approach would not sacrifice the quality of the AV Calculator. The stability and functionality of the AV Calculator has improved every year, and we believe there are diminishing returns to receiving public comments on specific versions of it at this time. This is particularly evident given that we receive fewer than 10 comments on average each year on the draft AV Calculator. In addition, since the first AV Calculator was released for PY 2014, we have never made substantive changes in a final version of the AV Calculator for a plan year based on comments received on the draft version for that plan year, though this feedback is valuable to HHS and informs our decisions to update the AV Calculator in subsequent plan years. This decision to not make substantive changes to the final version of the AV Calculator is also partly influenced by the limited timeframe HHS would have to make substantive changes to the final AV Calculator.

Thus, changes from the draft to the final version of the AV Calculator have historically only included non-substantive amendments to correct and clarify language in the AV Calculator Methodology or to add frequently asked questions to the AV Calculator User Guide. Since these changes have historically been so minor, we believe the time delay required to effectuate those changes and release the final AV Calculator by the end of the first quarter of the preceding plan year is less valuable to issuers than releasing the final version sooner. Under this approach, we would leave open the rare possibility that HHS could reissue another final version of the AV Calculator for a plan year if HHS discovers the AV Calculator contains an error that materially impacts the functionality or accuracy of that version of the AV Calculator. Although this has never happened to date, under the current framework of releasing both a

draft and final version of the AV Calculator, if we had discovered a material error in the final version, we also would have reissued a corrected, final version.

Under this approach, we would still seek public comment on the AV Calculator for a plan year generally and would still consult with the American Academy of Actuaries, as well as the National Association of Insurance Commissioners. We would consider this feedback for incorporation into the following year's AV Calculator.

In order to maximize the benefits of this approach, we intend to make this change effective starting with the release of the 2026 AV Calculator. We believe there will be minimal effect in effectuating this change with the 2026 AV Calculator because we intend to base the 2026 AV Calculator substantially on the final 2025 AV Calculator, and do not plan to make any material changes to it.

We seek comment on this approach.

6. Standardized Plan Options (§ 156.201)

HHS proposes to exercise its authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to make updates to its approach to standardized plan options for PY 2026. Specifically, we propose to make minor updates to the plan designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis range* for each metal level. While we generally propose to maintain a high degree of continuity with the approaches to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices (87 FR 27310 through 27322, 88 FR 25847 through 25855, and 89 FR 26357 through 26362, respectively), we also propose to amend § 156.201 by adding paragraph (c) to provide that an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, which includes section 1311, for, among other matters, the offering of QHPs through such Exchanges.

Standardized options were first introduced in the 2017 Payment Notice (81 FR 12289 through 12293). These plan designs were updated in the 2018 Payment Notice (81 FR 94107 through 94112). The 2018 Payment Notice (81 FR 94118) also introduced the authority for HHS to differentially display these plans on *HealthCare.gov,* which allowed consumers the ability to filter plan options to view only standardized options and receive an accompanying message explaining how standardized options differed from non-standardized options. The 2018 Payment Notice also introduced standardized option differential display requirements for approved web-broker and QHP issuer enrollment partners using a direct enrollment pathway to facilitate consumer enrollment through an FFE or SBE–FP—including both the Classic DE and EDE Pathways.

These plans were then discontinued in the 2019 Payment Notice (83 FR 16974 through 16975). However, the discontinuance was challenged in the United States District Court for the District of Maryland. On March 4, 2021, the court decided City of Columbus, *et al.* v. Cochran.[220] The court reviewed nine separate policies HHS had promulgated in the 2019 Payment Notice, vacating four of them. The court specifically vacated the portion of the 2019 Payment Notice that ceased HHS' practice of designating some plans in the FFEs as ''standardized options.''

As a result, in part 3 of the 2022 Payment Notice (86 FR 24140, 24264), HHS announced its intent to engage in rulemaking under which it would propose to resume standardized plan options in PY 2023. President Biden's Executive Order on Promoting Competition in the American Economy (86 FR 36987) also directed HHS to implement standardized plan options to facilitate the plan selection process for consumers on the Exchanges. We thus reintroduced standardized plan option requirements in the 2023 Payment Notice (87 FR 27310 through 27322) to enhance the consumer experience, increase consumer understanding, simplify the plan selection process, combat discriminatory benefit designs that disproportionately impact disadvantaged populations, and advance health equity.

We made these requirements applicable to FFE and SBE–FP issuers offering QHPs in the individual market. We exempted FFE and SBE–FP issuers offering QHPs in the small group market as well as issuers in State Exchanges from these requirements. We also exempted issuers of QHPs in FFEs and SBE–FPs that were already required to offer standardized plan options under State action taking place on or before January 1, 2020, such as issuers in the State of Oregon,[221] from the requirement to offer the standardized plan options specified by HHS in rulemaking.

In the 2023 Payment Notice (87 FR 27312), we finalized standardized plan options at the following metal levels: one bronze plan, one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan. We did not finalize standardized plan options for the AI/AN CSR plan variations as provided for at § 156.420(b) given that the cost-sharing parameters for these plan variations are already largely specified.

In the 2023 Payment Notice (87 FR 27312), we finalized two sets of standardized plan options to accommodate different States' cost sharing laws. Specifically, the first set of standardized plan options applied to all FFE and SBE–FP issuers, except issuers in Delaware, Louisiana, and Oregon. The second set of standardized plan options applied only to issuers in Delaware and Louisiana to accommodate these two States' specialty prescription drug cost sharing laws.

We designed these standardized plan options to resemble the most popular QHP offerings that millions of consumers were already enrolled in by taking the following steps: selecting the most popular cost-sharing type for each benefit category; selecting enrollee-weighted median values for each of these benefit categories based on PY 2022 cost sharing and enrollment data; modifying these plans to ensure they were able to comply with State cost sharing laws; and decreasing the AVs for these plan designs to be at the floor of each AV *de minimis range,* primarily by increasing deductibles. We also used the following four tiers of prescription drug cost sharing in these standardized plan options: generic drugs, preferred brand drugs, non-preferred brand drugs, and specialty drugs.

We also resumed the differential display of standardized plan options on *HealthCare.gov* pursuant to § 155.205(b)(1), including those standardized plan options required under State action taking place on or before January 1, 2020. In addition, we resumed enforcing the standardized plan option display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or

[220] 523 F. Supp. 3d 731 (D. Md. 2021).

[221] See Or. Admin. R. 836–053–0009.

SBE–FP—including both the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively.

As such, web-brokers and QHP issuers have been required to differentially display standardized plan options in accordance with the requirements under § 155.205(b)(1) in a manner consistent with how standardized plan options were displayed on *HealthCare.gov,* unless we approve a deviation. Any requests from web-brokers and QHP issuers seeking approval of an alternate differentiation format were reviewed based on whether the same or a similar level of differentiation and clarity would be provided under the requested deviation as was provided on *HealthCare.gov.*

In the 2024 Payment Notice (88 FR 25847 through 25855), we maintained a high degree of continuity with our approach to standardized plan options finalized in the 2023 Payment Notice. However, in contrast to the policy finalized in the 2023 Payment Notice, we finalized for PY 2024 and subsequent plan years to no longer include a standardized plan option for the non-expanded bronze metal level—primarily due to AV constraints and the infeasibility of designing such a plan. As such, we finalized standardized plan options for the following metal levels: one bronze plan that meets the requirement to have an AV up to 5 points above the 60 percent standard, as specified in § 156.140(c) (known as an expanded bronze plan), one standard silver plan, one version of each of the three income-based silver CSR plan variations, one gold plan, and one platinum plan.

We also removed the regulation text language stating that standardized plan options for the AI/AN CSR plan variations as provided for at § 156.420(b) were not required, to clarify that while issuers must, under § 156.420(b), continue to offer such plan variations based on standardized plan options, those plan variations would themselves not be standardized plan options based on designs specified in rulemaking.[222] We again finalized two sets of standardized plan options applying to issuers in the same sets of States as in the 2023 Payment Notice.

In the 2025 Payment Notice (89 FR 26357 through 26362), we once more maintained a high degree of continuity with the approach to standardized plan options finalized in the 2024 Payment Notice. In particular, in accordance with § 156.201(b), we finalized standardized plan options for the same metal levels as in the 2024 Payment Notice. We again did not finalize standardized plan options for the AI/AN CSR plan variations as provided for at § 156.420(b) but continued requiring issuers to offer these plan variations for all standardized plan options offered. We once more finalized two sets of standardized plan options with the same sets of designs applying to issuers in the same sets of States as in the 2023 and 2024 Payment Notices.

We refer readers to the preambles to the 2023, 2024, and 2025 Payment Notices discussing § 156.201 (87 FR 27310 through 27322, 88 FR 25847 through 25855, and 89 FR 26357 through 26362, respectively) for more detailed discussions regarding our approaches to standardized plan options in previous plan years.

For PY 2026, we propose to continue following the approach finalized in the 2024 Payment Notice concerning standardized plan option metal levels, and to otherwise maintain a high degree of continuity with our approach to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices. We once more propose to make minor updates to the plan designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level. Our proposed updates to plan designs for PY 2026 are detailed in tables 11 and 12, later in this section.

We propose to maintain this high degree of continuity for several reasons. Primarily, we believe maintaining a high degree of continuity will reduce the risk of disruption for all involved interested parties, including issuers, agents, brokers, States, and enrollees. We continue to believe that making major departures from the standardized plan option designs finalized in the 2023, 2024, and 2025 Payment Notices could result in significant changes that may create undue burden for interested parties.

For example, we continue to believe that if the standardized plan options that we create vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost sharing for services they rely upon differs substantially from the previous year. Ultimately, we continue to believe that consistency in standardized plan options is important to allow issuers and enrollees to become accustomed to these plan designs. As such, the proposed standardized plan options include only modifications to the deductibles and maximum out-of-pocket limits (MOOPs) for several metal levels, but do not otherwise include modifications to the cost sharing structures.

Although we propose to continue to maintain a high degree of continuity with our approach to standardized plan options in previous years, we propose to amend § 156.201 to add paragraph (c) to require an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

This proposal is based in part on our experience with the meaningful difference standard, which was previously codified at § 156.298. The meaningful difference standard was introduced in the 2015 Payment Notice (79 FR 13813 through 13814), revised in the 2017 Payment Notice (81 FR 12312 and 12331), and subsequently discontinued and removed from the regulation in the 2019 Payment Notice (83 FR 17027). The meaningful difference standard was originally intended to enhance the consumer experience on *HealthCare.gov* by preventing duplicative plan offerings and limiting plan proliferation.

Under the original meaningful difference standard introduced in the 2015 Payment Notice (79 FR 13813 through 13814), a plan within a service area and metal tier would be considered meaningfully different from other plans if a reasonable consumer (the typical consumer buying health insurance coverage) would be able to identify at least one material difference among six key characteristics between the plan and other plans to be offered by the same issuer: (1) cost sharing; (2) provider networks; (3) covered benefits (including prescription drugs); (4) plan type (for example, HMO or PPO); (5) health savings account eligibility; and (6) self- only, non-self-only, or child-only plan offerings. Under the original standard, if HHS determined that the plan offerings at a particular metal level within a county were limited, plans submitted for certification at that metal level within that county were not subject to the meaningful difference requirement.

Under the meaningful difference standard revised in the 2017 Payment Notice (81 FR 12312 and 12331), a plan was considered to be ''meaningfully different'' from other plans in the same service area and metal level if the plan had at least one of the following characteristics: a difference in network ID; a difference in formulary ID; a

[222] See QHP Certification Standardized Plan Options FAQs, *https://www.qhpcertification.cms.gov/s/Standardized%20Plan%20Options%20FAQs.*

difference in MOOP type (specifically, an integrated medical and drug MOOP versus a separated medical and drug MOOP); a difference in deductible type (specifically, an integrated medical and drug deductible versus a separated medical and drug deductible); a difference in the number of in-network tiers; a $500 or more difference in MOOP; a $250 or more difference in deductible; or a difference in benefit coverage. The decision to discontinue the meaningful difference standard in the 2019 Payment Notice was made primarily due to the decreased number of plan offerings on the Exchanges.

We propose a meaningful difference standard for PY 2026 and subsequent plan years at § 156.201(c) because several issuers in recent years have offered indistinguishable standardized plan options, and we believe issuers may continue to do so in future plan years partly because the number of non-standardized plan options that issuers can offer is limited in accordance with § 156.202(b). We do not believe it benefits consumers for issuers to offer identical standardized plan options, or standardized plan options that do not differ in meaningful ways, within the same product network type, metal level, and service area. In addition, permitting issuers to offer identical standardized plan options or standardized plan options that do not differ in meaningful ways runs counter to our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process. Allowing issuers to offer duplicative standardized plan options could cause significant consumer confusion and unnecessary plan proliferation if the trend continues unabated.

As such, under this proposal, although issuers would continue to be permitted to offer multiple standardized plan options within the same product network type, metal level, and service area, these standardized plan options would be required to have meaningfully different benefit coverage, provider networks, and/or formularies. For the purposes of this proposed standard, for PY 2026 and subsequent plan years, we would consider a standardized plan option with a different product, provider network, and/or formulary ID to be meaningfully different, similar to the version of the standard from the 2017 Payment Notice.

In particular, in that rule, we explained that a plan within a service area and metal tier would be considered meaningfully different from other plans if a reasonable consumer (the typical consumer buying health insurance coverage) would be able to identify at least one material differences among several key characteristics between the plan and other plans to be offered by the same issuer. Provider networks and covered benefits (including prescription drugs) were included among the list of key characteristics that would result in a material difference between plans and a plan therefore being considered meaningfully different.

If an issuer submitted two standardized plan options within the same product network type, metal level, and service area both with the same products, provider networks, and formulary IDs, we would not certify both of these plans. For example, we anticipate that we would seek feedback from the issuer regarding which plan to certify, assuming the issuer meets all other certification requirements. We also note that for the purposes of this proposed standard, we would not consider differences in plan variant marketing names, the availability of different language access features, or the administration of the plan by different vendors in determining whether two or more standardized plan options are meaningfully different.

If this policy is finalized as proposed, we would monitor whether issuers are seeking certification of plans that technically meet this standard but are nearly identical. If we determined that issuers were attempting to circumvent this standard in this manner, we would consider proposing in future rulemaking a version of this meaningful difference standard that would require greater variation among plans beyond product, provider network, and/or formulary IDs. We note that we are not proposing such a standard for PY 2026 and subsequent plan years at this time because, assuming issuers do not attempt to circumvent this standard as explained above, we believe that that this proposed policy would likely be sufficient to ensure that issuers' standardized plan offerings support our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process.

We seek comment on our proposed approach to standardized plan options for PY 2026, including amending § 156.201 to add paragraph (c).

TABLE 11: 2026 Proposed Standardized Plan Options Set One (For All FFE and SBE-FP Issuers, Excluding Issuers in Delaware, Louisiana, and Oregon)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.42%	70.01%	73.07%	87.04%	94.11%	78.04%	88.03%
Deductible	$7,500	$6,000	$3,000	$700	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,200	$8,900	$7,400	$3,300	$2,200	$8,200	$5,200
Emergency Room Services	60%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	60%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	$90*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	$120*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health & Substance Use Disorder Outpatient Office Visit	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	60%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	60%	40%	40%	30%	25%*	25%	$30*
X-rays/Diagnostic Imaging	60%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	60%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	60%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician & Services	60%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	$50	$40*	$40*	$20*	$15*	$30*	$10*
Non-Preferred Brand Drugs	$100	$80	$80	$60	$50*	$60*	$50*
Specialty Drugs	$500	$350	$350	$250	$150*	$250*	$150*

*Benefit category not subject to the deductible.

TABLE 12: 2026 Proposed Standardized Plan Options Set Two (For Issuers in Delaware and Louisiana)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.42%	70.01%	73.09%	87.07%	94.09%	78.02%	88.01%
Deductible	$7,500	$6,000	$3,000	$700	$0	$2,000	$0
Annual Limitation on Cost Sharing	$9,200	$8,900	$7,400	$3,300	$2,400	$8,300	$5,300
Emergency Room Services	60%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	60%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	$90*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	$120*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health & Substance Use Disorder Outpatient Office Visit	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	60%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	$60*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	60%	40%	40%	30%	25%*	25%	$30*
X-rays/Diagnostic Imaging	60%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	60%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	60%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician & Services	60%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	$50	$40*	$40*	$20*	$5*	$30*	$10*
Non-Preferred Brand Drugs	$100	$80	$80	$60	$10*	$60*	$50*
Specialty Drugs	$150	$125	$125	$100	$20*	$100*	$75*

*Benefit category not subject to the deductible.

7. Non-Standardized Plan Option Limits (§ 156.202)

We propose to exercise our authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to amend § 156.202(b) and (d) to properly reflect the flexibility that issuers have operationally been permitted since the introduction of non-standardized plan option limits to vary the inclusion of distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage categories under the non-standardized plan option limit in accordance with § 156.202(c)(1) through (3).

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, which includes section 1311, for, among other things, the offering of QHPs through such Exchanges.

In the 2024 Payment Notice (88 FR 25855 through 25865), we finalized requirements under § 156.202(a) and (b) limiting the number of non-standardized plan options that issuers of QHPs can offer through Exchanges on the Federal platform (including SBE–FPs) to four non-standardized plan options per product network type (as described in the definition of ''product'' at § 144.103), metal level (excluding catastrophic plans), inclusion of dental and/or vision benefit coverage, and service area for PY 2024, and two for PY 2025 and subsequent years.

In the 2025 Payment Notice (89 FR 26362 through 26375), we finalized an exceptions process under § 156.202(d) and (e) permitting FFE and SBE–FP issuers to offer more than two non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent plan years, if issuers demonstrate that these additional non-standardized plans offered beyond the limit at § 156.202(b) have specific design features that would substantially benefit consumers with chronic and high-cost conditions and meet certain other requirements.

In the 2025 Payment Notice (88 FR 26365 through 26366), we also clarified that the example included in the 2024 Payment Notice that illustrated issuers' flexibility to vary the inclusion of dental and/or vision benefit coverage in accordance with § 156.202(c) under the non-standardized plan option limits at § 156.202(a) and (b) failed to properly distinguish between the adult and pediatric dental benefit coverage categories.

In particular, in the 2024 Payment Notice (88 FR 25858), we stated that for PY 2025, for example, an issuer would be permitted to offer two non-standardized gold HMOs with no additional dental or vision benefit coverage, two non-standardized gold HMOs with additional dental benefit coverage, two non-standardized gold HMOs with additional vision benefit coverage, and two non-standardized gold HMOs with additional dental and vision benefit coverage, as well as two non-standardized gold PPOs with no additional dental or vision benefit coverage, two non-standardized gold PPOs with additional dental benefit coverage, two non-standardized gold PPOs with additional vision benefit coverage, and two non-standardized gold PPOs with additional dental and vision benefit coverage, in the same service area.

However, in the 2025 Payment Notice, we clarified that in PY 2024, issuers had the ability to vary the inclusion of dental and/or vision benefit coverage (including varying the inclusion of the distinct adult and pediatric dental benefit coverage categories), such that issuers could offer plans in the manner reflected in table 13, below, instead of in the more limited manner reflected in the incomplete example in the 2024 Payment Notice.

In the 2025 Payment Notice, we affirmed that issuers continued to retain this flexibility for PY 2025 and subsequent years. We thus explained that under the non-standardized plan option limit of two for PY 2025 and subsequent years, if an issuer desired to offer the theoretical maximum number of non-standardized plans, and if that issuer varied the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage in these plans in accordance with the flexibility provided for at § 156.202(c)(1) through (3), that issuer could offer a theoretical maximum of 16 plans in a given product network type, metal level, and service area in the manner demonstrated in table 13. Furthermore, we explained that if an issuer offered QHPs with two product network types (for example, HMO and PPO), that issuer could offer a theoretical maximum of 32 plans in a given metal level and service area in the manner demonstrated in table 13.

TABLE 13: Issuer Flexibility Under the Non-Standardized Plan Option Limit of Two for PY 2025 and Subsequent Years

Plan	Network Type	Cost Sharing Structure	Adult Dental	Pediatric Dental	Adult Vision
1	HMO	A			
2	HMO	A	Covered		
3	HMO	A		Covered	
4	HMO	A			Covered
5	HMO	A		Covered	Covered
6	HMO	A	Covered		Covered
7	HMO	A	Covered	Covered	
8	HMO	A	Covered	Covered	Covered
9	HMO	B			
10	HMO	B	Covered		
11	HMO	B		Covered	
12	HMO	B			Covered
13	HMO	B		Covered	Covered
14	HMO	B	Covered		Covered
15	HMO	B	Covered	Covered	
16	HMO	B	Covered	Covered	Covered
17	PPO	C			
18	PPO	C	Covered		
19	PPO	C		Covered	
20	PPO	C			Covered
21	PPO	C		Covered	Covered
22	PPO	C	Covered		Covered
23	PPO	C	Covered	Covered	
24	PPO	C	Covered	Covered	Covered
25	PPO	D			
26	PPO	D	Covered		
27	PPO	D		Covered	
28	PPO	D			Covered
29	PPO	D		Covered	Covered
30	PPO	D	Covered		Covered
31	PPO	D	Covered	Covered	
32	PPO	D	Covered	Covered	Covered

As such, we propose to amend the regulation text at § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since we introduced non-standardized plan option limits to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage under the non-standardized plan option limit at § 156.202(b) in accordance with § 156.202(c)(1) through (3) for PY 2025 and subsequent plan years.

In particular, we propose to amend § 156.202(b) to properly distinguish between adult dental benefit coverage at § 156.202(c)(1) and pediatric dental benefit coverage at § 156.202(c)(2), such that an issuer offering QHPs in an FFE or SBE–FP, for PY 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), in any service area.

Consistent with our proposed amendment of § 156.202(b), we propose a conforming amendment to § 156.202(d) to provide that, for PY 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in the issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage, and service area.

We propose these modifications to align the regulation text of § 156.202(b) and (d) with the existing flexibility that issuers have been operationally permitted since the non-standardized plan option limit was introduced in the 2024 Payment Notice.[223]

We seek comment on these proposed modifications.

8. Essential Community Provider Reviews for States Performing Plan Management (§ 156.235)

Under § 156.235, we propose to conduct Essential Community Provider (ECP) certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions effective beginning in PY 2026.[224]

Section 1311(c)(1)(C) of the ACA directs HHS to establish by regulation certification criteria for QHPs, including criteria that require QHPs to include within health insurance plan networks those ECPs, where available, that serve predominately low-income, medically-underserved individuals. Federal ECP standards were first detailed in the Exchange Establishment Rule (77 FR 18310) and codified at § 156.235. ECP certification reviews under § 156.235 ensure medical QHP and stand-alone dental plan (SADP) issuers include in their provider networks a sufficient number and geographic distribution of ECPs, where available.

HHS has relied on State ECP certification reviews for the certification of QHPs in FFEs in States that perform plan management functions since PY 2015 due to system limitations in the Systems for Electronic Rates & Forms Filing (SERFF),[225] which does not have unique network and service area IDs reliably associated with issuers' ECP data. From PY 2015 to PY 2024, prior to HHS' implementation of the user interface logic for ECPs in the Health Insurance Oversight System (HIOS) Marketplace Plan Management System (MPMS),[226] HHS received ECP data via the ECP/Network Adequacy (NA) Template[227] and SERFF. The ECP/NA Template was an Excel template created by HHS to provide to FFE issuers for collection and submission of both ECP and NA data. While issuers in FFE States would submit the ECP/NA Template with ECP data to HHS directly, issuers in FFEs in States performing plan management functions would not use the ECP/NA Template, but rather submit the ECP data to SERFF.[228] Since there was no reliable mechanism for HHS to convert ECP data received from SERFF back into the ECP/NA Template for review and analysis of the data, HHS could not conduct ECP reviews for issuers in FFEs in States performing plan management functions and therefore relied on States to perform those ECP certification reviews. In the SERFF data, each plan has its own ECP template with its own set of ECPs and networks. The SERFF data does not allow HHS to conduct accurate ECP evaluations of each issuer's networks because multiple networks can share the same sequence number within the SERFF data, making them indistinguishable from each other in the issuer's SERFF binder. Initially, HHS designed a workaround to merge the SERFF issuer templates across each plan and remove duplicate entries to allow HHS to conduct the review at the plan level; but this workaround still did not allow for independent evaluation of each issuer's provider networks that share the same sequence number.

As a result of HHS' system design enhancements via MPMS, HHS is now able to collect ECP data directly from issuers in States performing plan management functions, enabling HHS to conduct ECP evaluations of each issuer's network. Starting with certification reviews for PY 2025, issuers seeking certification of plans as QHPs in FFEs, including in States performing plan management functions, can now enter their ECP data in the HIOS MPMS using the ECP user interface. Because ECP data can now be collected directly in MPMS from issuers applying for certification of plans as QHPs in FFEs in States performing plan management functions, HHS will now be able to independently review the ECP data for such issuers.

Now, the MPMS ECP user interface also allows issuers in FFEs, including in States performing plan management functions, to validate data before submission to their States, improving data submission to the State as well as providing HHS with each issuer's provider network. Therefore, HHS will now be able to assess validated ECP data, improving the accuracy and efficiency of the QHP certification process.

It was always HHS' intent to implement operational capabilities that would allow for more efficient and accurate ECP reviews. As a result, we propose to harness the flexibilities afforded by MPMS to conduct Federal ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States that perform plan management functions beginning with certification reviews for PY 2026. This proposal would allow HHS to review, evaluate, analyze, and compare provider networks across various FFE States. HHS would also consider challenges FFE issuers face across various provider networks and ECP categories, such as provider shortages or facility closures. As proposed, issuers applying for certification of plans as QHPs in FFEs, including in States performing plan management functions, would be evaluated against the same requirements and standards. FFE issuers in States with limited plan management staff or resources would be given the same ECP support, guidance, and monitoring of ECP deficiencies as other FFE issuers.

This proposal would provide more consistent oversight of ECP data across all FFEs. Federal ECP reviews would help ensure all medical QHP and SADP issuers applying for certification of plans as QHPs in FFEs, including in States performing plan management functions, include sufficient provider networks. This proposal would allow HHS to strengthen ECP data integrity in the FFEs by validating all ECP data before they are submitted and displayed on the FFEs, thereby supporting consumer access to vitally important medical and dental services and health equity for low-income and medically underserved consumers.

We seek comment on this proposal.

9. Quality Improvement Strategy (§ 156.1130)

We propose to share aggregated, summary-level Quality Improvement Strategy (QIS) information publicly on an annual basis beginning on January 1, 2026, with information QHP issuers submit during the PY 2025 QHP Application Period. We do not propose any revisions to the regulation text to codify this proposal.

[223] CMS. (2024, April 10). 2025 Final Letter to Issuers in the Federally-facilitated Exchanges. *https://www.cms.gov/files/document/2025-letter-issuers.pdf.*

[224] Twelve FFEs operate in States performing plan management functions: Delaware, Hawaii, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

[225] Systems for Electronic Rates & Forms Filing (SERFF) is a portal utilized by States for form submittal, document management, and review.

[226] HIOS MPMS is a web application where users can validate plan data as well as submit their QHPs and SADPs to CMS for annual review and certification.

[227] OMB Control Number 0938–1415: Essential Community Provider-Network Adequacy (ECP/NA) Data Collection to Support QHP Certification (CMS–10803).

[228] For PY 2025 there were 13 FFEs that operate in States performing plan management functions: Delaware, Hawaii, Illinois, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

Section 1311(c)(1)(E) of the ACA specifies that to be certified as a QHP for participation on an Exchange, each health plan must implement a QIS described in section 1311(g)(1) of the ACA. Section 1311(g)(1) of the ACA describes this strategy as a payment structure that provides increased reimbursement or other incentives for improving health outcomes of plan enrollees, and the implementation of activities to prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities. Section 1311(g)(2) of the ACA requires the Secretary to develop guidelines associated with the QIS in consultation with health care quality experts and interested parties, including periodic reporting to the applicable Exchange of the activities that the plan has conducted to implement the QIS, as described in section 1311(g)(3) of the ACA. In the 2016 Payment Notice (80 FR 10844 through 10845), we issued regulations at § 156.1130(a) and (c) to direct eligible QHP issuers to implement and report on their QIS for each QHP offered in an Exchange, and to submit data annually to evaluate compliance with the standards for a QIS in a manner and timeline specified by the Exchange, respectively.[229] In addition, in the Exchange Establishment Rule (77 FR 18324 and 18415), we finalized regulations at § 155.200(d) that direct Exchanges to evaluate each QIS, and § 156.200(b)(5) that direct QHP issuers to implement and report on a QIS consistent with ACA section 1311(g) standards as QHP certification criteria for participation in an Exchange.

The CMS National Quality Strategy,[230] launched in 2022, builds on previous efforts to improve quality across the health care system. We continue to use a variety of levers across the agency, including but not limited to quality measurement, public reporting and quality improvement programs, to improve health care quality for all. One of the four priority areas of the CMS National Quality Strategy is to promote alignment and coordination across programs and care settings and to improve quality and health outcomes across the care journey.[231] By developing aligned approaches across quality programs, we can improve coordination and comparisons across programs and across the continuum of care and build the evidence base for quality interventions to support identifying disparities in care. Across Medicare, Medicaid and Exchange quality programs and initiatives, we promote sharing health care quality information with consumers, providers, researchers and others using different methods such as the Care Compare website,[232] and program experience reports. Specifically, for the Quality Rating System (QRS) program, we share a summary of quality ratings for each plan year in an annual Results at a Glance report.[233] Additionally, we share information pertaining to both the QRS and QHP Enrollee Experience Survey programs with the public annually through the same report.[234] Our proposal to share aggregated, summary-level QIS information publicly is consistent with the goal of these Marketplace Quality Initiatives (MQIs) to share information publicly and is in alignment with agency efforts to drive innovation and advance quality improvement across the Exchanges.

Since 2017, we have been collecting QIS information from QHP issuers on the FFEs. Over the years, we have received feedback from issuers, States, and Technical Expert Panel representatives about the benefits of sharing QIS data more broadly to promote transparency, improve engagement of best practices across QHP issuers, and provide consumers with useful information about quality improvement efforts by QHP issuers on the FFEs. Therefore, recognizing the general interest in this information, and consistent with the general authority set forth in section 1701(a)(8) of the PHS Act,[235] we propose to release annually, in a report format, the following aggregated, summary-level QHP issuer data: (1) value-based payment models used in QHPs offered by the issuer; (2) QIS topic area; (3) QIS market-based incentive types; (4) clinical areas addressed by QIS; (5) QIS activities; and (6) QRS measures used in QIS. We do not receive QIS data from State Exchanges or SBE–FPs and would not collect QIS data from State Exchanges or SBE–FPs or their respective issuers under this proposal. As such, the report would provide information on QIS programs adopted by issuers offering QHPs in the FFEs.

We believe that this proposal would promote transparency of data and drive innovation and quality improvement across Exchanges. Sharing QIS data publicly would also strengthen alignment across CMS quality reporting and value-based incentive programs, including the MQI programs, and would encourage learning to inform best practices for quality improvement across Exchanges, QHP issuers, researchers, and health care quality communities. Additionally, we believe that this proposal would increase accountability for QHP issuers through transparency of quality improvement goals, encourage State Exchanges to share QIS information from their State Exchange issuers publicly, and support HHS' mission to achieve optimal health and well-being for all individuals.

We acknowledge there may be concerns related to the potential sharing of proprietary and/or confidential information. However, we do not intend to share confidential or proprietary information from a QHP issuer and would only share QIS data that is de-identified and in summary and aggregate form. We would maintain compliance with CMS privacy policies, and to address potential confidentiality concerns, we would carefully redact and omit confidential data when data are released aggregately and in a summary format.

We seek comment on this proposal. In particular, we seek comment on the types of QHP issuer QIS data to release in an annual report, on the proposed approach and timeline for release of a QIS summary report with aggregated QIS data, and other potential mechanisms to present QIS information publicly in a manner that is informative to issuers and consumers.

10. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

We propose to amend § 156.1220(a) to codify a second, new materiality threshold for HHS–RADV appeals,[236] hereafter referred to as the materiality threshold for rerunning HHS–RADV

[229] Refer to OMB control number 0938–1286.

[230] The CMS National Quality Strategy for Quality Improvement in Health Care available at *http://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[231] Id.

[232] See Care Compare at *https://www.cms.gov/medicare/quality/physician-compare-initiative.*

[233] See, for example, Health Insurance Exchanges Quality Rating System (QRS) for Plan Year (PY) 2024: Results at a Glance, available at *https://www.cms.gov/files/document/health-insurance-exchanges-qrs-program-plan-year-2024-results-glance.pdf.*

[234] See, for example, Health Insurance Exchanges Quality Rating System (QRS) for Plan Year (PY) 2024: Results at a Glance, available at *https://www.cms.gov/files/document/health-insurance-exchanges-qrs-program-plan-year-2024-results-glance.pdf.*

[235] Section 1701(a)(8) of the PHS Act, codified at 42 U.S.C. 300u(a)(8), provides general authority to the Secretary of HHS to foster exchange of health-related information to consumers and others.

[236] For the purposes of this proposal, ''appeals'' refers to all three steps of the administrative appeals process as listed in § 156.1220, which includes the request for reconsideration, informal hearing, and review by the Administrator of CMS.

results.[237] This proposal would codify a standard for when HHS would take action to rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal. We propose to make amendments to § 156.1220 to add a new paragraph (a)(2)(i) to provide that HHS would rerun HHS–RADV results in response to an appeal when the impact to the filing issuer's (that is, the issuer who submitted the appeal) HHS–RADV adjustments to State transfers is greater than or equal to $10,000, and we propose to apply this second, new materiality threshold beginning with 2023 benefit year HHS–RADV.[238]

An issuer has the opportunity to submit a request for reconsideration to contest its HHS–RADV second validation audit results (if applicable) or its error rate calculations in accordance with § 156.1220(a)(1)(vii) and (viii).[239] [240] An issuer can also request an informal hearing before a CMS hearing officer to appeal HHS' reconsideration decision in accordance with § 156.1220(b) and may request review by the CMS Administrator of the CMS hearing officer's discretion as outlined in § 156.1220(c). Currently, § 156.1220(a)(2) specifies that an issuer may file an HHS–RADV request for reconsideration if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge from the issuer for the benefit year, or $10,000, whichever is less. However, the current regulations do not specify when HHS is required to rerun HHS–RADV results in response to an appeal. This allows for the possibility of an appeal being filed that, if granted, in its totality would result in an impact of $10,000 or 1 percent of the applicable payment or charge for the issuer for the benefit year, whichever is less. HHS may therefore be put into a position to rerun HHS–RADV results if any portion of that appeal is accepted by HHS, even if that portion has a much smaller impact than the materiality threshold to file the appeal. Based on our experience operating HHS–RADV since the 2017 benefit year, we determined there would be a benefit from codifying a second materiality threshold to address when HHS would be required to rerun HHS–RADV results in response to successful appeals. This second materiality threshold would promote the stability of HHS–RADV and avoid considerable expenditures to rerun HHS–RADV results in situations where the filing issuer only accrues a very minor financial benefit (in this case defined as less than $10,000), if any, and where there is a non-material impact on State transfers in a State market risk pool. By way of example, assume an issuer submits an appeal of its SVA results or HHS–RADV error rate calculation that contests the determination for 35 HCCs, of which 3 HCCs are validated during the appeal process. In this example, assume that the consequences of those modified results impact other issuers (non-filing issuers) and shift the national benchmarks to determine error rate outliers in HHS–RADV, but the filing issuer receives a benefit of only $100. In this situation, applying the proposed materiality threshold for rerunning HHS–RADV results, HHS would not spend the significant resources for itself and issuers to rerun HHS–RADV, recalculate HHS–RADV adjustments to State transfers, re-release HHS–RADV results, complete another discrepancy and appeal window for the reissued results, engage in netting and send new invoices to issuers, collect charges and redistribute payments for the reissued HHS–RADV adjustments to State transfers in response to the successful appeal. In contrast, if the impact on the filing issuer was material (that is, greater than or equal to $10,000), the impact on other issuers (non-filing issuers) would also likely be more significant, and HHS would engage in the significant effort to re-run HHS–RADV results.

We believe the adoption of the proposed additional materiality threshold to codify a standard for when HHS would rerun HHS–RADV results is necessary and appropriate because HHS–RADV is unique in comparison to other ACA financial programs, such as APTC, where the outcome of a successful appeal only impacts the filing issuer because an issuer's amount of APTC does not impact other issuers.[241] Instead, an HHS–RADV appeal has the potential to impact all issuers nationwide who participated in the applicable benefit year's HHS–RADV.[242] More specifically, because HHS–RADV uses HCC-based group failure rates from all issuers that participate in HHS–RADV for the benefit year being audited, the inclusion or exclusion of even one HCC can result in a change in the national program benchmarks that apply to all issuers nationwide who participated in HHS–RADV in the applicable benefit year. The national program benchmarks are used to create confidence intervals for outlier identification and calculate outlier issuers' error rates. Therefore, changes to the national program benchmarks may result in changes to the outlier status or error rates of all issuers, due not to an error in their own data, but as a result of an HHS decision on another issuer's HHS–RADV appeal. In these situations when there are minor adjustments, this would result in all issuers in States with an error rate outlier receiving small changes to their HHS–RADV adjustments to State transfers as a result of one issuer's successful HHS–RADV appeal.

To further explain the uniqueness of HHS–RADV, we want to compare the existing HHS–RADV appeal materiality threshold at § 156.1220(a)(2) to that of the EDGE data discrepancies in § 153.630(d)(2). Under § 153.630(d)(2), upon receipt of an EDGE data discrepancy, the impact is first analyzed by HHS, and the entirety of an impact must reach the materiality threshold in order for HHS to take further action. However, unlike HHS–RADV appeals that have the potential to impact the national HHS–RADV results, EDGE data discrepancies typically only impact the issuers at the State market risk pool level and therefore, they do not have the potential to trigger the same national level of adjustments that can be

[237] For purposes of this proposal, rerunning HHS–RADV results involves recalculating all national program benchmarks and issuers' error rate results, reissuing issuers' error rate results, conducting discrepancy reporting and appeal windows for the reissued results, applying the reissued error rates to the applicable benefit year's State transfers, and invoicing, collecting, and distributing any additional changes to the HHS–RADV adjustments to State transfers.

[238] The appeal window for 2023 benefit year HHS–RADV is expected to open in July 2025, after the tentative July publication of the Summary Report of 2023 Benefit Year HHS–RADV Adjustments to 2023 Benefit Year Risk Adjustment Transfers. Therefore, we are proposing to adopt and apply the materiality threshold for rerunning HHS–RADV results beginning with 2023 benefit year HHS–RADV. See the *2023 Benefit Year HHS–RADV Activities Timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.*

[239] Issuers are not permitted to file a request for reconsideration or appeal the results of the IVA audit. See 81 FR 94106 and 84 FR 17495.

[240] Consistent with § 156.1220(a)(4)(ii), an HHS–RADV request for reconsideration may be requested only if, to the extent the issue could have been previously identified, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in § 153.630(d)(2) and (3), it was so identified, and remains unresolved.

[241] The EDGE data discrepancies that can arise in States where the HHS-operated risk adjustment program applies have a more limited reach and only impact the State market risk pool with the discrepancy.

[242] The impact of successful HHS–RADV requests for reconsideration or appeals on HHS–RADV results and HHS–RADV adjustments to risk adjustment State transfers on all participating issuers also differs from that of high-cost risk pool audits, discrepancies, and appeals. Any high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans, actionable discrepancies, or successful appeals are used to reduce high-cost risk pool charges for that national high-cost risk pool in the next applicable benefit year for which high-cost risk pool payments have not already been calculated. See 87 FR 27253.

triggered by successful HHS–RADV appeals. When evaluating HHS–RADV requests for reconsideration, the entirety of the reconsideration request is used to determine materiality, regardless of what portion of that reconsideration request is found to have merit. For example, an issuer can include 25 HCCs in an HHS–RADV request for reconsideration, and upon review, HHS can find that one of them has merit and the other 24 do not. Under the existing materiality threshold at § 156.1220(a)(2), the materiality determination is based on the impact that accepting all 25 HCCs in the request for reconsideration would have on HHS–RADV results, rather than the impact of the one HCC determined to be meritorious.

Because an HHS–RADV appeal can impact national program benchmarks and the HHS–RADV results and HHS–RADV adjustments of issuers nationally, we believe that the adoption of this proposed additional materiality threshold to specify when HHS would rerun HHS–RADV results would help ensure stability of HHS–RADV results for all issuers. In particular, HHS–RADV adjustments to State transfers already occur 2 years after the end of the applicable benefit year. Rerunning HHS–RADV results in response to a successful appeal could occur years later depending on the complexity of the issues raised and whether the matter involves an informal hearing under § 156.1220(b) or a request for CMS Administrator review under § 156.1220(c). After the initial issuance of HHS–RADV adjustments, issuers generally have already closed their books for the applicable benefit year, and we are concerned that rerunning HHS–RADV results as a result of a successful HHS–RADV appeal that would not meet the proposed additional materiality threshold would require issuers to reopen their books years later, increasing burden and creating instability for issuers of risk adjustment covered plans to account for minor adjustments. In these situations, we are of the opinion that the benefit of the minor adjustment would be outweighed by the costs and burdens associated with rerunning HHS–RADV results to account for the additional minor adjustment to State transfers.

We also note that it is burdensome to HHS to rerun HHS–RADV results, especially in situations where there is a small financial impact. Because of the budget-neutral nature of the HHS-operated risk adjustment program, including HHS–RADV, the costs associated with rerunning HHS–RADV are passed onto the issuers in the form of the risk adjustment user fees. Therefore, we believe that creating an additional materiality threshold for rerunning HHS–RADV results recognizes that an appeal must have a meaningful financial impact to justify the costs and burdens to HHS and issuers of rerunning HHS–RADV results. This would balance the policy goals of ensuring that processing errors, the incorrect application of the relevant methodology, or mathematical errors in HHS–RADV that have a material impact are appropriately addressed, while minimizing burden on issuers and HHS and promoting the stability of State transfers by not rerunning HHS–RADV results when there would be minor adjustments. For all of these reasons, we propose to adopt an additional materiality threshold for HHS–RADV appeals to provide a standard for when HHS would rerun HHS–RADV results. To align with § 153.710(e), we propose to apply this materiality threshold for rerunning HHS–RADV results based on the financial impact on the filer as we believe that issuers submit HHS–RADV appeals with the expectation that their acceptance would meaningfully benefit them financially. Thus, we believe that structuring the threshold based on the financial impact on the filer would ensure that HHS–RADV results are being rerun in situations where the impact of the HHS–RADV appeal is meaningful to the issuer that triggered the process and would have a material impact on other issuers that participate in HHS–RADV in the applicable benefit year.

We also reaffirm under this proposed policy that if the impact of the appeal meets the proposed materiality threshold for rerunning HHS–RADV results (that is, greater than or equal to $10,000 to the filing issuer's HHS–RADV adjustments for the applicable benefit year), HHS would rerun the HHS–RADV results for that benefit year. However, if the impact of the appeal is less than proposed materiality threshold for rerunning HHS–RADV results (that is, less than $10,000 to the filing issuer's HHS–RADV adjustment), then HHS would take no further action. That is, HHS would not rerun HHS–RADV results or make any changes to the HHS–RADV adjustments for the filing issuer or other issuers that participated in HHS–RADV for that benefit year if the new proposed materiality threshold is not met.

We solicit comments on the proposed materiality threshold for rerunning HHS–RADV results, including the proposed dollar amount for the materiality threshold and whether that dollar amount should be a higher or lower dollar amount or subject to an annual inflation adjustment amount, as well as the proposed applicability of this threshold beginning with 2023 benefit year HHS–RADV.

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

1. Definitions (§ 158.103)

We propose to amend § 158.103 by adding a definition of ''qualifying issuer.'' See subsection E.2 below for the discussion of this proposal.

2. Reimbursement for Clinical Services Provided to Enrollees (§§ 158.140, 158.240)

We propose to amend § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year (MLR reports due in 2027). We also propose to amend § 158.240(c) to add an illustrative example of how qualifying issuers would calculate the amount of rebate owed to each enrollee to accurately reflect how such issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers, as well as to make a conforming amendment to clarify that the current illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers.

Section 2718 of the PHS Act and the implementing regulations at 45 CFR part 158 require health insurance issuers offering group or individual health insurance coverage to submit an annual report to the Secretary of HHS concerning their MLR and issue an annual rebate to enrollees if the issuer's MLR is less than the applicable MLR standard established in sections 2718(b)(1)(A)(i) and (ii) of the PHS Act. Under section 2718 of the PHS Act, an issuer's MLR is defined as the ratio of (a) incurred claims and quality improvement activity expenses, to (b) premium revenue after subtracting taxes and licensing and regulatory fees and accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341 1342, and 1343 of the ACA. The statute also defines the total amount of an issuer's annual rebate as an amount equal to the product of the amount by which the applicable MLR standard exceeds the issuer's MLR, multiplied by the issuer's premium revenue after subtracting taxes and licensing and regulatory fees and accounting for payments or receipts for

risk adjustment, risk corridors, and reinsurance under sections 1341 1342, and 1343 of the ACA.

In contrast, section 1342(c) of the ACA provides that allowable costs shall be reduced by any risk adjustment payments in the numerator of the risk corridors calculation.[243] In order to preserve consistency between these two programs, we finalized an approach in the 2014 Payment Notice (78 FR 15504) that accounted for all premium stabilization program [244] amounts, other than reinsurance contribution fees, in a way that would not have a net impact on the adjusted earned premium revenue used in the calculation of the MLR denominator as defined in § 158.130. Specifically, in the 2014 Payment Notice, we explained that to account for premium stabilization program amounts as an adjustment to earned premium under § 158.130(b)(5), net risk adjustment program receipts, net risk corridors program receipts, and reinsurance program payments would be added to total premium and then subtracted from adjusted earned premium. Section 158.140(b)(4) also provided that premium stabilization amounts, other than reinsurance contribution fees, must adjust incurred claims in the numerator of the MLR calculation defined in § 158.221, in a manner similar to the adjustment of allowable costs in the risk corridors formula set forth in § 153.500. As stated in the 2014 Payment Notice, we found that this approach adhered to the statutory construct of the MLR formula in section 2718 of the PHS Act, which we believe provides flexibility as to whether to account for the effects of collections or receipts for the premium stabilization programs in determining revenue (the denominator) or costs (the numerator) of the MLR formula, while also aligning with the treatment of risk adjustment transfer amounts and reinsurance payments in the calculation of risk corridors payments and charges under section 1342 of the ACA.

While most commenters on the 2014 Payment Notice proposed rule (77 FR 73187) supported the proposal to treat premium stabilization program amounts as an adjustment to incurred claims in the numerator of the MLR calculation, some commenters noted that risk adjustment transfer amounts are calculated based on the statewide average premium in a market, and asserted that it would, therefore, be more appropriate to include risk adjustment transfer amounts as a net adjustment to earned premium in § 158.130, which is included in the denominator of the MLR calculation in § 158.221(c). We recognized the validity of both perspectives in the 2014 Payment Notice, noting that either approach could be implemented in accordance with the statutory requirements for the MLR calculation set forth in section 2718 of the PHS Act, and finalized the proposal to treat premium stabilization amounts as an adjustment to incurred claims in the numerator of the MLR calculation to ensure consistency between the MLR and the risk corridors programs.

We recognize that although we generally assume that plans are pricing for average risk, our experience has shown that some issuers with plans with especially high or low claims costs may not necessarily price their offerings commensurate to these costs. While treating risk adjustment transfer amounts as either an adjustment to incurred claims in the numerator of the MLR calculation or an adjustment to premiums in the denominator of the MLR calculation may not significantly impact issuers with claims costs and premiums ratios that approximate the MLR standard and that closely approximate average risk, if an issuer's plan offerings are significantly mispriced or if its earned premiums are influenced by external factors, such as State subsidies, such an issuer could be in a position of owing rebates that are a substantial portion of its premium under the current MLR calculation methodology, despite also incurring very high claims costs and receiving large risk adjustment payments. In rare cases, these high rebate amounts may result in solvency concerns for these types of issuers with very high-risk populations and high claims expenses.

While many complex factors influence an issuer's underwriting position, our internal analysis suggests that issuers with unusual business models characterized by ratios of risk adjustment payments to earned premium that are approximately 50 percent or higher may owe disproportionately large MLR rebates that could impact solvency. In these circumstances, we believe that the way the current MLR methodology functions is misaligned with one of the primary statutory goals of the program, which is to ensure that consumers receive value for their premium dollars, as issuers with especially high-risk populations spend a significant proportion of their revenue paying medical claims and may nonetheless also owe rebates that make continued operation in their current markets untenable. Consistent with section 2718(c) of the PHS Act, the standardized methodologies for calculating an issuer's MLR ''shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.'' We believe that modifying the treatment of risk adjustment transfer amounts in the MLR and rebate calculations for these issuers such that these amounts have a net impact on the MLR denominator rather than on MLR numerator would mitigate the solvency and stability concerns for this small subset of issuers that offer different types of plans with unique business models. Specifically, this proposed change would support the viability of issuers that offer different types of plans with unique business models that focus on underserved communities with significant rates of serious health conditions and that may disproportionately rely on risk adjustment payments, as opposed to premiums, for revenue.

HHS has in the past exercised its authority under section 2718(c) of the PHS Act to take into account the special circumstances of different types of plans by providing adjustments to increase the MLR numerator for ''mini-med'' and ''expatriate'' plans,[245] student health insurance plans,[246] as well as for QHPs that incurred Exchange implementation costs [247] and certain non-grandfathered plans (that is, ''grandmothered'' plans).[248] This authority has also been exercised to recognize the special circumstances of new plans [249] and smaller plans,[250] as well as the new and different types of plans that provide ''shared savings'' to consumers who

[243] Section 1342 of the ACA and the implementing regulations at 45 CFR part 153 established a temporary risk corridors program applicable to QHP issuers in the individual and small group (or merged) markets for the 2014, 2015, and 2016 benefit years.

[244] The premium stabilization programs refer to the reinsurance, risk corridors, and risk adjustment programs established by the ACA. See section 1341 of the ACA (transitional reinsurance program), section 1342 of the ACA (risk corridors program), and section 1343 of the ACA (risk adjustment program).

[245] See 45 CFR 158.221(b)(3) for ''mini-med'' plans and 45 CFR 158.221(b)(4) for ''expatriate'' plans. See also the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act Interim Final Rule, 75 FR 74864, 74872 (December 1, 2010).

[246] See 45 CFR 158.221(b)(5). See also the Student Health Insurance Coverage Final Rule, 77 FR 16453, 16458 through 16459 (March 21, 2012).

[247] See 45 CFR 158.221(b)(7). See also the 2015 Market Standards Rule, 79 FR 30240, 30320 (May 27, 2014).

[248] See 45 CFR 158.221(b)(6). See also 79 FR 30320 (May 27, 2014).

[249] See 45 CFR 158.121. See also 75 FR 74872 through 74873 (Dec. 01, 2010) and the 2018 Payment Notice, 81 FR 94058, 94153 through 94154 (Dec. 22, 2016).

[250] See 45 CFR 158.230 and 158.232. See also 75 FR 74880 (Dec. 01, 2010).

choose lower-cost, higher-value providers.[251]

Consistent with this approach, we propose to exercise our authority to account for the special circumstances of the small subset of issuers that offer different types of plans with unique business models that receive risk adjustment payments and that are unable to reduce premiums sufficiently to meet the MLR standard without risking insolvency (hereinafter referred to as ''qualifying issuers''). We propose to exercise this authority to narrowly extend flexibility for the manner in which risk adjustment transfer amounts must be reported by these qualifying issuers. Specifically, we propose to amend § 158.103 to add a definition of ''qualifying issuer'' to mean an issuer whose ratio of net payments related to the risk adjustment program under section 1343 of the ACA to earned premiums prior to accounting for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs (as described in § 158.130(b)(5)) in a relevant State and market is greater than or equal to 50 percent. We also propose to modify § 158.140(b)(4)(ii) to no longer apply net risk adjustment receipts as an adjustment to the incurred claims amount that is used to calculate the MLR numerator defined in § 158.221(b) for such qualifying issuers. We do not propose to make any changes to the definition of premium revenue in § 158.130.

Under this proposal, we would modify the calculation of the MLR denominator and rebates as described in the 2014 Payment Notice such that for qualifying issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium. The effect of these proposed changes would be to remove these offsetting adjustments (the addition and the subtraction that offset each other) to earned premium in the MLR denominator and rebate calculations, such that these qualifying issuers' risk adjustment transfer amounts would have a net impact on the MLR denominator and rebate calculations in § 158.221(c) and § 158.240(c), respectively. We also propose to make a conforming amendment to § 158.240(c) to clarify that the existing illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers, and to add an illustrative example in a new paragraph (c)(3) of how qualifying issuers would determine the amount of rebate owed to each enrollee, to accurately reflect how qualifying issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers.

We note that we are not proposing any changes that would alter the current treatment of Federal transitional reinsurance amounts in the MLR formula. Section 2718 of the PHS Act specified that Federal transitional reinsurance amounts under section 1341 of the ACA be accounted for in the denominator of the MLR calculation, while the Federal transitional reinsurance program expired after the 2016 benefit year, audit activities continue [252] and could result in changes to the amounts previously provided. In addition, maintaining this treatment is consistent with the NAIC recommendations for the treatment of payments under State reinsurance programs (for example, those provided to issuers through a State-based reinsurance program established under section 1332 waivers), which are accounted for as an adjustment to incurred claims in § 158.140(b)(2)(i) and (ii).

We additionally note that HHS no longer collects charges or makes payments to issuers for the temporary Federal risk corridors program established in section 1342 of the ACA, which expired after the 2016 benefit year, and that therefore, the policy goal of aligning similar components in the risk corridors and MLR calculation no longer exists.[253] We have provided guidance to issuers regarding the reporting of risk corridors amounts for the applicable reporting years through MLR Reporting Instructions and other guidance, most recently on December 30, 2020.[254] While we recognize that the MLR and rebate calculation methodology finalized in the 2014 Payment Notice used the same variables to account for risk adjustment and risk corridors payments and risk adjustment and risk corridors charges, we do not believe that it is necessary to amend the regulations at §§ 158.130, 158.221(c), and 158.240(c) to modify the treatment of the Federal risk corridors amounts that are no longer being paid or collected. In addition, for consistency with the statutory language and our maintenance of the references to Federal transitional reinsurance amounts, we are similarly retaining the references to risk corridors in the formula for the MLR calculation.

In sum, we propose that for qualifying issuers, risk adjustment transfer amounts would be a net adjustment to the denominator, rather than the numerator, of the MLR calculation as follows:

If (ra/p) > or = 50%;

Adjusted MLR = [(i + q − s + nc − rc)/{(p + s − nc + rc) − t − f − (s − nc + rc) − na + ra}] + c

Where,

i = incurred claims
q = expenditures on quality improving activities
p = earned premiums
t = Federal and State taxes
f = licensing and regulatory fees including transitional reinsurance contributions
s = issuer's transitional reinsurance receipts
na = issuer's risk adjustment related payments
nc = issuer's risk corridors related payments
ra = issuer's risk adjustment related receipts
rc = issuer's risk corridors related receipts
c = credibility adjustment, if any

For a qualifying issuer whose MLR falls below the minimum MLR standard in a State and market, we propose to calculate the MLR rebate in § 158.240(c) as follows:

If (ra/p) > or = 50%;

Rebates = (m − a) * [(p + s − nc + rc) − t − f − (s − nc + rc) − na + ra]

Where:

m = the applicable minimum MLR standard for a particular State and market
a = issuer's MLR for a particular State and market.

We note that, under this proposal, the proposed alternate MLR and rebate methodologies would only apply to qualifying issuers. For all other issuers, the current MLR and rebate methodologies codified at § 158.140 and § 158.240 would continue to apply. We propose that these amendments would be applicable beginning with the 2026 MLR reporting year (MLR reports due in 2027), in order to enable issuers that are or may be able to meet the definition of qualifying issuer to reflect the amendments in their premium rates.

[251] See 45 CFR 158.221. See also the Transparency in Coverage Final Rule, 85 FR 72158, 72246 (Nov. 12, 2020).

[252] See Transitional Reinsurance Program Payment Audits, available at: *https://www.cms.gov/center-consumer-information-and-insurance-oversight.*

[253] On April 27, 2020, the Supreme Court ruled in *Maine Community Health Options* v. *United States,* 140 S. Ct. 1308 (2020), 590 U.S. (2020), that section 1342 of the ACA created an enforceable government obligation to pay risk corridors amounts as calculated under the risk corridors formula. Since that time, the United States has made payments from the Judgment Fund to issuers for their previously unpaid risk corridors amounts.

[254] See CMS. (2020, December 30). Insurance Standards Bulletin Series—Treatment of Risk Corridors Recovery Payments in the Medical Loss Ratio and Rebate Calculations. *https://www.cms.gov/files/document/mlr-guidance-rc-recoveries-and-mlr-final.pdf.*

We request comment on all aspects of this proposal. Specifically, we request comment on the definition of ''qualifying issuer,'' and whether issuers should satisfy additional criteria to qualify for this flexibility. We also request comment on whether the proposed alternate MLR and rebate methodologies that would apply to qualifying issuers would create any inappropriate incentives for issuers that are unable to accurately price their products or reduce administrative costs. Finally, we request comment on impacts to other issuers that are not ''qualifying issuers'' and potential market distortions that may arise if the proposed flexibility for MLR and rebate calculations is not extended to all issuers in applicable markets.

We are also considering an alternative approach that would modify § 158.140(b)(4)(ii) to no longer apply net risk adjustment receipts as an adjustment to the incurred claims amount that is used to calculate the MLR numerator defined in § 158.221(b) for all issuers subject to MLR requirements, which, as noted above, we believe to be consistent with the construction of the MLR formula in section 2718 of the PHS Act. Under this alternative approach, we would not make any changes to the definition of premium revenue in § 158.130, or to the regulatory treatment of Federal reinsurance or risk corridors in the MLR formula. Similar to the proposal above, under this alternative approach, we would modify the calculation of the MLR denominator and rebates as described in the 2014 Payment Notice such that for all issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium. The effect of this alternative approach would be that risk adjustment transfer amounts would have a net impact on the MLR denominator and rebate calculations in § 158.221(c) and § 158.240(c), respectively. This alternative approach would allow us to streamline MLR reporting in light of the expiration of the risk corridors program after the 2016 benefit year. In addition, this alternative approach would align MLR with the accounting approach used for risk adjustment transfers in State financial reporting, which accounts for these amounts in premium.[255]

Under this alternative approach, risk adjustment transfer amounts would be a net adjustment to the denominator, rather than the numerator, of the MLR calculation, for all issuers, as follows:

$$\text{Adjusted MLR} = [(i + q - s + nc - rc)/\{(p + s - nc + rc) - t - f - (s - nc + rc) - na + ra\}] + c$$

Where,

i = incurred claims
q = expenditures on quality improving activities
p = earned premiums
t = Federal and State taxes
f = licensing and regulatory fees including transitional reinsurance contributions
s = issuer's transitional reinsurance receipts
na = issuer's risk adjustment related payments
nc = issuer's risk corridors related payments
ra = issuer's risk adjustment related receipts
rc = issuer's risk corridors related receipts
c = credibility adjustment, if any

For an issuer whose MLR falls below the minimum MLR standard in a State and market, we would calculate the MLR rebate in § 158.240(c) as follows:

$$\text{Rebates} = (m - a) * [(p + s - nc + rc) - t - f - (s - nc + rc) - na + ra]$$

Where,

m = the applicable minimum MLR standard for a particular State and market
a = issuer's MLR for a particular State and market.

We believe that both the proposal and the alternative approach present a valid means of accounting for the impact of premium stabilization program amounts in the MLR and rebate calculations. Because most issuers are above the threshold for paying MLR rebates, we do not believe that the alternative approach would materially impact rebate payments for most issuers. However, for some issuers that are either below or close to the MLR standard, the alternative approach could result in larger rebate payments, particularly for issuers that owe risk adjustment charges and that have plan designs that result in premiums that are lower than the market average. We recognize the possibility that some of these issuers may further adjust premiums in response to this alternative approach if it were finalized. We are not proposing this alternative approach as we believe that the more narrow, tailored proposal to provide this flexibility only for qualifying issuers is sufficient to maximize availability of coverage options while remaining consistent with the statutory objective of section 2718 of the PHS Act, which is to ensure that consumers receive value for their premium dollars. The more narrow, tailored proposal would also produce a smaller reduction in rebate payments to consumers than the alternative approach and would cause less disruption to the industry.

We request comment on all aspects of this alternative approach, including on ways that this alternative approach could potentially influence issuers' rebate positions, plan composition, and pricing decisions. Finally, we request comment on potential impacts of this alternative approach on consumers.

F. Severability

As demonstrated by the number of distinct programs addressed in this rulemaking and the structure of this proposed rule in addressing them independently, HHS generally intends the rule's provisions as finalized to be severable from each other. For example, the proposed rule outlines proposed payment parameters and provisions for the HHS-operated risk adjustment and data validation programs, 2026 user fee rates for issuers in these programs, and changes to the BHP payment calculations. It includes proposed modifications to the initial and second validation audit processes and addresses HHS' authority to take enforcement action against lead agents at insurance agencies for violations of HHS' Exchange standards and requirements. The rule also addresses certification standards, ECP reviews, public sharing of aggregated, summary-level QIS information on an annual basis, and proposed revisions to the MLR reporting and rebate requirements for qualifying issuers that meet certain standards. It is HHS' intent that if any provision of these proposed rules, if finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, the rule shall be construed so as to continue to give maximum effect as permitted by law, unless the holding shall be one of utter invalidity or unenforceability. In the event a provision as finalized is found to be utterly invalid or unenforceable, HHS intends that that provision to be severable.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide a 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. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the agency.

[255] See, for example, NAIC, Supplemental Health Care Exhibit Instructions for Part 2, Line 1.1.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Wage Estimates

To derive wage estimates, we generally use data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for the cost of fringe benefits and overhead) for estimating the burden associated with the ICRs.[256] Table 14 presents the median 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 14: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Median Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Business Operations Specialists, All Other	13-1199	38.26	38.26	76.52
Health Information Technologists and Medical Registrars	29-9021	30.28	30.28	60.56
Compliance Officer	13-1041	36.38	36.38	72.76

B. ICRs Regarding the Initial Validation Audit (IVA) Sample—Enrollees Without HCCs, Removal of the FPC, and Neyman Allocation (§ 153.630(b))

Beginning with the 2025 benefit year of HHS–RADV, we propose to exclude enrollees without HCCs from the IVA sampling methodology, to remove the FPC from IVA sampling,[257] and to replace the source of the Neyman allocation data with the most recent 3 years of consecutive HHS–RADV data with results that have been released before HHS–RADV activities for the benefit year begin. Specifically, these proposals would exclude enrollees without HCCs (stratum 10 enrollees that do not have HCCs nor RXCs and RXC-only enrollees in strata 1 through 3) from IVA sampling, remove the FPC such that issuers with 200 or more enrollees in strata 1 through 9 would have IVA sample sizes of 200 enrollees and issuers with less than 200 enrollees in strata 1 through 9 would have IVA sample sizes equal to their population of enrollees with HCCs, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to HHS–RADV data. By removing enrollees without HCCs from IVA sampling, the Neyman allocation would only apply to enrollees with HCCs in strata 1 through 9 in the IVA sample.

These proposals are intended to improve the validity of our IVA sampling assumptions and sampling precision and would decrease burden on issuers when implemented in combination. As noted in section III.B.6 of this rule, the proposed changes to the IVA sampling methodology would result in increased sample sizes for some smaller issuers that are subject to the FPC and assigned IVA sample sizes less than 200 enrollees under the current methodology. However, sample size is not necessarily indicative of issuer burden in HHS–RADV, as the driving factor of burden is the number of enrollee medical records that must be retrieved and reviewed for the IVA sample. Overall, the proposed IVA sampling methodology in this rule alters the allocation of strata sample sizes within the IVA sample, ultimately resulting in relatively fewer enrollees from medium or high-risk strata, who have more medical records to review, being selected for the IVA sample. Consequently, under these proposed changes, the average number of medical records reviewed per enrollee in the IVA sample and the total number of medical records reviewed per issuer would decrease.

The currently approved information collection (OMB Control Number 0938–1155/Expiration April 30, 2025) for conducting the IVA takes into account that the issuer must review the IVA sample and determine which enrollees will require medical records to validate their HCCs and details the processes the issuer must undertake to obtain medical records for their enrollees selected for the IVA sample. In the currently approved information collection, we estimate an upper limit of 650 issuers submitting samples of 200 enrollees for HHS–RADV for any given benefit year, five medical record requests per enrollee in the IVA sample size and three HCCs to be reviewed by a certified medical coder per enrollees with HCCs, which leads to an aggregate burden of conducting IVAs of approximately 1,663,729 hours and $116,963,821.[258] Given the changes to the IVA sample under the proposed policies in this rule and recent HHS–RADV data, we estimate an upper limit of 600 issuers

[256] See Department of Labor. (2024, April 3). Bureau of Labor Statistics, Occupational Employment *and Wage* Statistics, *May 2023 Occupation Profiles. https://www.bls.gov/oes/current/oes_stru.htm.*

[257] In the current IVA sampling methodology, a Finite Population Correction factor is used to calculate a target IVA sample size less than 200 enrollees for issuers with less than 4,000 enrollees.

[258] OMB Control No: 0938–1155 (exp. April 30, 2025). *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202308-0938-015.*

submitting samples of 200 enrollees for HHS–RADV for any given benefit year.[259] We estimate an approximate average of two medical records reviewed and two HCCs reviewed per enrollee in the IVA sample.

For our monetary and hourly burden estimates, we are incorporating labor and wage costs from the most recent premium stabilization programs information collection, ''Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals'' (OMB Control Number 0938–1155/Expiration April 30, 2025). Based on an analysis that applies the proposed changes to remove enrollees without HCCs from IVA sampling, remove the FPC, and use HHS–RADV data in the Neyman allocation beginning with 2025 benefit year HHS–RADV, approximately 200 enrollees in an issuer sample will require medical records to validate HCCs, with approximately two medical record requests per enrollee (approximately 400 medical record requests per issuer) if these policies are finalized as proposed.[260] We estimate it will take a business operations specialist (occupation title ''Business Operations Specialists, All Other'' at an hourly wage rate of $76.52) approximately 1 hour to complete, review, and conduct follow-up on each medical record request (20 minutes each to complete each medical record request, review the response to each medical record request, and to conduct further follow-up on each medical record request). For each issuer, we anticipate the burden would be approximately 400 hours at a cost of $30,608. For an estimated 600 issuers required to submit samples for HHS–RADV for any given benefit year, we anticipate that the aggregate burden of completing medical record reviews will be approximately 240,000 hours and $18,364,800.

Based on a review of enrollee-level EDGE data for the 2017–2021 benefit years and the proposed changes to the IVA sampling methodology in this rule, we have determined that for enrollee with HCCs, the average number of HCCs to be reviewed by a certified medical coder per enrollee would be approximately two HCCs if these policies are finalized as proposed. Additionally, based on HHS–RADV audit experience, we estimate that it may cost approximately $272.52 ($60.56 per hour for 4.5 hours on average) for a certified medical coder to review the medical record documentation for one enrollee with roughly two HCCs. For 200 enrollees with HCCs in an issuer's IVA sample, the total cost to each issuer would be $54,504 (for 900 hours). In some cases, a secondary review by a senior certified medical coder (occupation title ''Health Information Technologists and Medical Registrars'' at an hourly wage rate of $60.56 per hour) will be needed to re-review approximately one-third of the medical record documentation required during the first review. Thus, a senior certified medical coder would need to review medical documentation for the equivalent of approximately 66 enrollees with HCCs in an issuer sample. We estimate that the total cost to each issuer would be approximately $17,986.32 ($60.56 per hour for 4.5 hours per enrollee). For this review and secondary review, the total cost to each issuer would be approximately $72,490.32 (1,197 total hours).

These proposals will not affect the review of demographic and enrollment information, as we will continue to validate demographic and enrollment information for a subsample of up to 50 enrollees from the audit sample, or the RXC review, as the audit entity must review RXCs for all adult enrollees in the audit sample with at least one RXC, and we continue to assume that an IVA will be performed on approximately 50 RXCs per issuer. As such, we are only changing our burden estimates of demographic and enrollment or RXC review to update the most recent BLS' median hourly wage estimates. We estimate that it may cost approximately $20.19 per enrollee ($60.56 per hour for 20 minutes) to validate demographic information for 50 enrollees in each audit sample totaling $1,009.33 per issuer. Similarly, we estimate that RXC validation for 50 enrollees would cost approximately $20.19 per RXC ($60.56 per hour for 20 minutes), totaling $1,009.33 per issuer. In addition, for each issuer, we expect it would require a compliance officer working 40 hours at $72.76 per hour, and 2 operations managers working a total of 80 hours at $97.38 per hour to make available to external medical coders associated with the initial validation audit entity claims documents for review of demographic information and RXC review (120 hours at a combined cost of $10,701).

For each issuer submitting audit findings for HHS–RADV in a given benefit year, the total burden for reporting, coding, and administration would be approximately 1,750.33 hours at a cost of $115,817.79 per issuer. For an estimated 600 issuers required to submit audit findings for HHS–RADV for any given benefit year, we anticipate that the aggregate burden of conducting IVAs will be approximately 1,050,200 hours and $69,490,672 beginning in 2025. This reflects an aggregate burden decrease of 613,529 hours and $47,473,149 from the existing aggregate burden estimate of approximately 1,663,729 hours and $116,963,821.

We seek comment on this proposal and the estimated burdens discussed above.

C. ICRs Regarding Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies (§ 155.220)

This proposal addresses HHS' authority to engage in compliance reviews of and take enforcement action against lead agents of insurance agencies in both FFE and SBE–FP States for misconduct or noncompliant activity at the agency level. We are not proposing any changes to regulations as the current regulatory framework and definitions supports this approach. Furthermore, this proposal only envisions collecting agency-level documentation, including but not limited to, training manuals, onboarding material, and marketing materials, from lead agents, in addition to the existing documentation collection [261] for agents, brokers, or web-brokers, to investigate potential misconduct or noncompliant behavior or activities. Therefore, this collection would fall under 5 CFR 1320.4(a)(2), stating collections of information ''. . . during the conduct of an [. . .] investigation'' are exceptions

[259] A total of 605 issuers participated in the HHS-operated risk adjustment program for the 2023 benefit year. However, some of these issuers are subject to exemptions from HHS–RADV under 45 CFR 153.630(g) and would not submit IVA samples for HHS–RADV. For example, any issuers at or below the materiality threshold for random and targeted sampling only participate in HHS–RADV approximately once every 3 years. Therefore, we use 600 issuers as a conservative upper limit of the number of issuers that could participate in a given benefit year of HHS–RADV. See the Summary Report on Individual and Small Group Market Risk Adjustment Transfers for the 2023 Benefit Year (July 22, 2024) available at: *https://www.cms.gov/cciio/programs-and-initiatives/premium-stabilization-programs/downloads/ra-report-by2023pdf.*

[260] This estimate is a decrease from the previous estimate of medical record requests per enrollee because the proposed changes to the IVA sampling methodology in the 2026 Payment Notice, if finalized as proposed, would generally result in relatively fewer enrollees sampled from medium- and higher-risk strata, which are generally composed of enrollees with more medical records whereby reducing our estimated number of medical records for review.

[261] This includes documentation of consumer review and confirmation of the accuracy of eligibility application information in compliance with 45 CFR 155.220(j)(2)(ii)(A)(2) and consumer consent documentation in compliance with 45 CFR 155.220(j)(2)(iii)(c).

to the ICR requirements.[262] The documentation that will be collected will solely relate to investigations of potential misconduct or noncompliant behavior or activities such that this exception would apply.

We seek comment on these assumptions.

D. ICRs Regarding Agent and Broker System Suspension Authority (§ 155.220(k))

This proposal would expand HHS' authority to suspend Exchange system access for agents and brokers under § 155.220(k)(3) to also include situations that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations or Exchange applicants or enrollees, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. Since this proposal would entail providing an opportunity for agents and brokers to submit evidence and information to demonstrate that the circumstances of the incident, breach, or noncompliance has been remedied or sufficiently mitigated to HHS' satisfaction, it would involve collecting documents from agents and brokers whose system access has been suspended. Depending on the circumstances leading to the system suspension, we anticipate receiving documentation of consumer consent and/or review and confirmation of the accuracy of the Exchange eligibility application information and assessing whether the documentation complies with § 155.220(j)(2)(ii) and (iii) for consumers cited in the suspension notice from agents and brokers we system suspend under § 155.220(k)(3). The system suspension authority in § 155.220(k)(3) is part of HHS' oversight and enforcement framework applicable to agents and brokers who participate in the FFEs and SBE–FPs. Therefore, this collection would fall under 5 CFR 1320.4(a)(2), stating collections of information ''. . . during the conduct of an [. . .] investigation'' are exceptions to the ICR requirements.[263] The documentation that would be collected would solely relate to investigations and responses to system suspensions, meaning this exception would apply.

We seek comment on these assumptions.

E. ICRs Regarding Updating the Model Consent Form (§ 155.220)

We are proposing amendments to the Model Consent Form created as part of the 2024 Payment Notice (88 FR 25809 through 25811). The existing Model Consent Form only provides a template for meeting the consent documentation and retention requirements of § 155.220(j)(2)(iii)(A)-(C). We are proposing to update that Model Consent Form to also include a template to meet the requirements under § 155.220(j)(2)(ii), which requires agents, brokers, and web-brokers to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to submission of the application to the FFE or SBE–FP. This proposal would only update the optional Model Consent Form that was created as part of the 2024 Payment Notice and adopted on June 30, 2023. The 2024 Payment Notice [264] considered the additional time it would take the assisting agent, broker, or web-broker to process and submit each consumer's eligibility application and those assumptions remain valid and are unchanged. We believe these assumptions remain as none of the regulatory requirements established by the 2024 Payment Notice are being changed and no new requirements are being added with this proposal. Therefore, this proposal would not impart extra time or costs to the assisting agent, broker, or web-broker. Agents, brokers, and web-brokers are already required to meet the requirements of § 155.220(j)(2)(ii) and (iii), meaning the time required to gather the documentation required by the 2024 Payment Notice requirements is already a part of every agent's, broker's, and web-broker's enrollment process. We do not believe the updated Model Consent Form would impose any additional burden on agents, brokers, web-brokers, or consumers, because usage of this Model Consent Form remains optional and this updated Model Consent Form is simply intended to provide a useable example of how agents, brokers, agencies and web-brokers may compliantly meet the documentation requirements already required by the 2024 Payment Notice. If agents, brokers, agencies or web-brokers elect to use this form, we do not anticipate that the updated Model Consent Form would take any longer to fill out than agent, broker, web-broker, or agency-created forms or other methods being already being utilized currently as the requirements for documentation are not changing from the documentation requirements that agents, brokers, agencies and web-brokers are already required to meet in their current agent, broker, web-broker or agency created forms or methods.

The proposed Model Consent Form would also include scripts agents, brokers, or web-brokers could utilize to meet the consumer consent and eligibility application review requirements finalized in the 2024 Payment Notice requirements when assisting consumers via an audio recording. The scripts would ensure agents, brokers, or web-brokers having verbal, recorded conversations with consumers discuss all the regulatory requirements with consumers. We do not anticipate these scripts would increase burden on any assisting agent, broker, web-broker or consumer as no regulatory requirements have been changed. As agents, brokers, and web-brokers should already be complying with these requirements, no additional costs would be borne by the agent, broker, or web-broker if using the updated Model Consent Form scripts. The scripts are merely meant to provide agents, brokers, and web-brokers guidance and clarification on how the consent documentation and eligibility application review documentation requirements can be met when having a verbal, recorded conversation with a consumer. The proposed scripts in the updated Model Consent Form are not mandatory and are not intended to limit or otherwise impact the agent, broker, or web-broker's ability to answer consumer questions about plan selection or other matters.

Finally, there is no anticipated increase in documentation collection burden on HHS based on the updated model consent form. We currently request documentation of consumer consent and eligibility application review for compliance reviews and, assuming agents, brokers, and web-brokers used the updated model consent form, that would not meaningfully impact the documentation collection or review by HHS.

If this proposal is finalized, the updated Model Consent Form discussed in this section would be submitted for OMB review and approval in the amended PRA package (OMB Control Number 0938–1438/Expiration date: June 30, 2026). We seek comment on these assumptions.

[262] 5 CFR 1320.4(a)(2).

[263] 5 CFR 1320.4(a)(2).

[264] 88 FR 25890 through 25891.

F. ICRs Regarding Notification of Two Year Failure To File and Reconcile Population (§ 155.305)

We are proposing to amend current regulation at § 155.305(f)(4) under which an Exchange needs to provide notification to either an enrollee or their tax filer (or both) who have been identified as having failed to file their Federal income taxes and reconcile their APTC after two consecutive tax years. This provision is not associated with an ICR under 5 CFR 1320.3(c) and not subject to the requirements of the PRA. We anticipate that the proposed amendment will not impact the information collection (OMB Control Number 0938–1207) burden for Exchanges.

G. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

As discussed in the preamble of this rule, we intend to increase transparency into Exchange operations by publishing annual State Exchange and SBE–FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment (OE) data reports. We estimate that there will be no additional costs or burdens on Exchanges associated with this proposal since this data is already collected through the Blueprint application (OMB Control Number: 0938–1172), SMART (OMB Control Number: 0938–1244), and Enrollment Metrics PRA (OMB Control Number: 0938–1119).

H. ICRs Regarding Essential Community Provider Certification Reviews (§ 156.235)

The proposal to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions effective beginning in PY 2026 continues our ECP data collection as permitted under the currently approved information collection (OMB Control Number: 0938–1187/Expiration date: June 30, 2025).

To satisfy the ECP requirement under § 156.235, medical QHP and SADP issuers must complete and submit ECP data as part of their QHP application, in which they must list the names and geographic locations of ECPs with whom they have contracted to provide health care services to low-income, medically underserved individuals in their service areas. These issuers must contract with a certain percentage, as determined by HHS, of the available ECPs in the plan's service area. This proposal, if finalized, would not significantly change the burden currently approved under OMB Control Number 0938–1415,[265] because the ECP data collected remains the same. Only the format in which the ECP information is submitted would be different. As described in the preamble, issuers in FFEs, including in States performing plan management functions, can now submit ECP data to HHS via MPMS. As a result of HHS system design enhancements via MPMS, HHS is now able to collect ECP data directly from issuers in FFEs in States performing plan management functions, enabling HHS to conduct independent ECP evaluations of each issuers' network.

I. ICRs Regarding Quality Improvement Strategy Information (§ 156.1130)

There is no information collection associated with this proposal and no changes are proposed to the QIS data collection requirements applicable to QHP issuers. QIS data collection from QHP issuers to the Exchange has been approved under OMB Control Number 0938–1286.

J. ICRs Regarding Medical Loss Ratio (§§ 158.103, 158.140, 158.240)

We propose to add a definition of ''qualifying issuer'' to § 158.103, amend § 158.140(b)(4)(ii) to no longer adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes for qualifying issuers, make conforming amendments to the rebate calculation example in § 158.240(c)(2), and add § 158.240(c)(3) to provide a rebate calculation example for qualifying issuers. To the extent issuers currently report their risk adjustment transfer amounts on their Annual MLR Reporting Form(s), we do not expect there to be any impact on the reporting burden, as the affected issuers would continue to report the same risk adjustment transfer amounts but would include them on different lines of the MLR Annual Reporting Form. The burden related to this information collection is currently approved under OMB Control Number: 0938–1164.

K. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 15: 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 ($)	Total Cost ($)
45 CFR 153.630(b)	0938-1155	600	600	-1,022.55	-613,529	-$47,473,149	-$47,473,149
TOTAL		600	600		-613,529	-$47,473,149	-$47,473,149

L. Submission of PRA-Related Comments

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

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

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule

[265] OMB Control Number 0938–1415: Essential Community Provider-Network Adequacy (ECP/NA) Data Collection to Support QHP Certification (CMS–10803).

and identify the rule [CMS–9888–P], the ICR's CFR citation, CMS ID number, and OMB Control Number.

ICR-related comments are due [**DATE**].

M. 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 preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule includes payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation programs, as well as 2026 user fee rates for issuers offering QHPs through FFEs and SBE–FPs. This proposed rule also includes proposed requirements related to modifications to the calculation of the BHP payment, changes to the IVA sampling approach and SVA pairwise means test for HHS–RADV, as well as proposed compliance reviews of and enforcement action against lead agents, proposed updates to the Model Consent Form, the authority for HHS to suspend agent and broker access to Exchange systems, consumer notification requirements, and proposed standards for an issuer to request the reconsideration of denial of certification as a QHP specific to the FFEs, proposed changes to the approach for conducting ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions, and proposed revisions to the MLR reporting and rebate requirements for qualifying issuers.

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), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, 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).

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). The April 6, 2023 Executive Order on Modernizing Regulatory Review [266] amends Section 3(f) of Executive Order 12866 to define a ''significant regulatory action'' as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for significant rules. OMB's OIRA has determined that this rulemaking is ''significant'' as measured by the $200 million threshold under section 3(f)(1). We have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf*), we have prepared an accounting statement in table 16 showing the classification of the impact associated with the provisions of this proposed rule.

This proposed rule implements standards for programs that would have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in Exchanges. We are unable to quantify all the benefits and costs of this proposed rule. The effects in table 16 reflect qualitative assessment of 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 17 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers.

[266] Office of the White House. (2023, April 6). *Executive Order on Modernizing Regulatory Review. https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/06/executive-order-on-modernizing-regulatory-review/.*

TABLE 16: Accounting Table

Benefits:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$39 million	2024	2 percent	2025-2029
Quantitative: • Cost savings of $47,473,149 annually for issuers for conducting IVAs due to IVA sampling methodology changes reducing the estimated number of medical records for review beginning with the 2025 benefit year of HHS-RADV. • Total cost savings of $1,884,632.40 annually for the 12 FFE States currently performing plan management functions associated with reduced administrative burden as proposed since they would no longer be responsible for ECP data review. • Reduced Federal costs by approximately $75,000 per year and administrative burden associated with the HHS-RADV materiality threshold proposal, as this proposal would eliminate situations wherein HHS is required to reissue HHS-RADV for all issuers when the impact is less than $10,000 beginning in 2025.				
Qualitative: • Decreased risk of adverse selection with respect to coverage of PrEP users, resulting in an increase in health equity among this population due to the proposal to incorporate PrEP in HHS risk adjustment adult and child models, as a new, separate type of model factor. • Improved education of tax filers and enrollees regarding the new two-tax year FTR requirements. • Improved processing by State Exchanges of enrollment data inaccuracies, which benefits consumers by ensuring accurate payment of APTCs by proposing to codify HHS' standard for reporting enrollment inaccuracies and for the State Exchange to resolve them. • Reduced enrollment barriers, particularly for low-income enrollees who would be disproportionately impacted by disruptions in coverage, associated with the proposal to allow issuers to implement a fixed-dollar premium payment threshold. • Increased compliance with AV de minimis ranges associated with the approach to release the AV Calculator earlier. • Increased transparency in Exchanges by publishing annual State Exchange and SBE-FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the OE data reports				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$3 million	2024	2 percent	2025-2029
Quantitative: • Cost increase for the medical review by approximately $1.5 million annually for the Federal government due to initial SVA subsample size increase beginning with the 2024 benefit year of HHS-RADV. • Annual cost increase of $500,000 to the Federal government for increases to SVA medical record review due to the proposed SVA pairwise means testing procedure resulting in more SVA subsamples being expanded for review beginning with the 2024 benefit year of HHS-RADV. • One-time cost of $250,000 to the Federal government to code modifications to the existing SVA pairwise means test in the Audit Tool beginning with the 2024 benefit year of HHS-RADV. • Annual costs of $134,000 to the Federal government to send initial direct FTR notices to the two-tax year FTR population starting in benefit year 2025. • Annual costs of $31,920 to State Exchanges for FTR notices for the two-tax year population. • Regulatory review costs of $1,963,438.75 for interested parties to review and analyze this proposed rule.				
Qualitative: • Not a significant increase in administrative burden or financial impact on the Federal government for ECP data review due to the proposal to conduct ECP certification reviews for plans offered by issuers in FFEs in States performing plan management functions beginning in PY 2026, due to using existing system infrastructure for the FFEs.				
Transfers:	Estimates	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	Primary: $1.098 billion	2024	2 percent	2025-2029

				2029
	Low: $909 million	2024	2 percent	2025-2029
	High: $1.186 billion	2024	2 percent	2025-2029

Quantitative:

- An estimated annual transfer of APTC of $481,477,453.60 from the Federal government to enrollees whose coverage would otherwise be terminated for non-payment as a result of the proposal to establish an optional fixed-dollar premium payment threshold beginning in 2025.
- Increase in FFE and SBE-FP user fee transfers from issuers to the Federal government of $644 million for benefit year 2026 compared to if the user fee level from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE-FP user fee transfers from issuers to the Federal government of $849 million in 2027, $852 million in 2028, and $854 million in 2029 if the proposed 2026 user fee level were maintained in subsequent years. Under the alternate FFE and SBE-FP user fee proposal, which reflects different enrollment assumptions, we estimate increases in FFE and SBE-FP user fee transfers compared to if the 2025 benefit year user fee level were maintained for 2026 and beyond from issuers to the Federal government within a range of $425 million to $690 million in 2026, $585 million to $950 million in 2027, $607 million to $985 million in 2028, and $629 million to $1.021 billion in 2029 if user fee rates in the alternate range were maintained in subsequent years.
- Annual cost of $8,155 associated with ECP enforcement action is transferred from the FFEs in States performing plan management functions to the Federal government in accordance with the proposal for HHS to conduct ECP reviews for these States.
- Reduced rebates paid by issuers to consumers or increased premiums collected by issuers from consumers of approximately $20 million annually beginning with the 2026 MLR reporting year associated with the proposal to add a definition of "qualifying issuer" to no longer adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes for qualifying issuers.

TABLE 17: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2026-2030, in billions of dollars[1]

Year	2026	2027	2028	2029	2030	2026-2030
Risk Adjustment and Reinsurance Program Payments	9	10	10	10	10	49
Risk Adjustment and Reinsurance Program Collections	-10	-10	-10	-10	-10	-50

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2023 to 2033. Table A-2. September 2023. *https://www.cbo.gov/system/files/2023-09/59273-health-coverage.pdf.*

1. BHP Methodology Regarding the Value of the Premium Adjustment Factor (42 CFR Part 600)

The aggregate economic impact of these proposed changes to the BHP payment methodology is estimated to be $0 in transfers for calendar year 2026 and all subsequent years. For the purposes of this analysis, we have assumed that two States would operate BHPs in 2026 since currently only two States operate BHPs, and we do not assume any more States would do so.

For the States currently operating BHPs, we do not anticipate these proposed changes to the payment methodology would affect future payments. We expect that these States would have fully implemented programs by 2026, and thus these proposed changes would not change the value of the PAF used in the payment

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

methodologies for these States in 2026 and beyond. If other States implemented a BHP and did so on a partial basis, the proposed changes would be expected to reduce Federal BHP payments compared to what they would be under current law. The changes in payments would depend on the number of people on BHP in the State, the QHP premiums in the State, and the level of adjustments added to the premiums to account for the CSRs.

2. Incorporation of PrEP Affiliated Cost Factor (ACF) in the HHS Risk Adjustment Adult and Child Models (§ 153.320)

We are proposing the incorporation of PrEP into the HHS risk adjustment adult and child models as part of a new proposed class of factors that reflect the costs associated with care that is not related to active medical conditions. This proposed class of factors, called the Affiliated Cost Factors (ACFs), which are detailed in the preamble discussion under 45 CFR part 153, will not result in any additional reporting burden for issuers. Because it will have some impact on risk adjustment State transfers, some issuers' State transfers will be impacted, either in a positive or in a negative manner, consistent with the budget-neutral nature of the HHS-operated risk adjustment program. As HHS is responsible for operating the risk adjustment program in all 50 States and the District of Columbia, we do not expect these policies to place any additional burden on State governments. The proposed model specifications in this rule result in limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the HHS-operated risk adjustment program. This proposal will help mitigate risk of adverse selection for coverage of PrEP users, resulting in increased health equity among this population.

3. Initial Validation Audit (IVA) Sampling Methodology Changes (§ 153.630(b))

Under § 153.630(b), we are proposing several changes to the IVA sampling methodology. Beginning with the 2025 benefit year of HHS–RADV, we propose to exclude enrollees without HCCs (enrollees in stratum 10 without HCCs nor RXCs and RXC-only enrollees in strata 1 through 3) from IVA sampling, remove the FPC such that issuers with 200 or more enrollees in strata 1 through 9 would have IVA sample sizes of 200 enrollees and issuers with less than 200 enrollees in strata 1 through 9 would have IVA sample sizes equal to their EDGE population of enrollees with HCCs, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin, beginning with benefit year 2025 HHS–RADV.

Although issuers are already required to provide the IVA Entities with all documentation necessary to complete HHS–RADV, the proposed changes to the IVA sample would ensure all enrollees in the IVA sample have at least one HCC on EDGE and therefore would have associated medical records that would need to be submitted. In the Collection of Information section of this proposed rule, we estimate the decrease in administrative burden that would result from the proposals to modify the IVA sample as the average number of medical records reviewed per enrollee in the IVA sample and the average number of medical records reviewed per issuer would decrease. We estimate that the aggregate burden of conducting IVAs would be approximately 1,050,200 hours and $69,490,672 beginning with 2025 benefit year HHS–RADV, which is an aggregate burden decrease of 613,529 hours and $47,473,149 from the existing aggregate burden estimate of approximately 1,663,729 hours and $116,963,821. We believe that these proposed changes to the IVA sampling methodology would result in more precise HHS–RADV results which are used to adjust risk scores and associated risk adjustment State transfers. While this could affect the adjustments to risk adjustment State transfers for an individual issuer, we do not expect an impact on aggregate risk adjustment State transfer adjustments because of the proposed modifications to the IVA sampling methodology.

4. Second Validation Audit (SVA) Pairwise Means Test (§ 153.630(c))

We propose to modify the pairwise means test to use a 90 percent confidence interval bootstrapping methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV. Because issuers are already required to provide the IVA and SVA Entities with all documentation necessary to complete the audits, the proposed changes to the pairwise means test that would increase the initial SVA subsample size to 24 enrollees and transition to a bootstrapping methodology using a 90 percent confidence interval would not directly increase burden on issuers. We believe that these proposed changes would increase the burden and costs to the Federal government of conducting the SVA. We estimate that increasing the initial SVA sample size from 12 to 24 enrollees would increase the annual costs of SVA medical review by approximately $1.5 million and that transitioning from the current t-test pairwise means testing procedure to a bootstrapped procedure would increase the annual cost of SVA medical review by approximately $500,000 as more issuers would be expanded to larger SVA sample sizes under a more sensitive pairwise means testing procedure. In addition, there would be a one-time cost of approximately $250,000 to code these modifications to the existing SVA pairwise means test in the Audit Tool. Any increase in SVA costs would increase the costs to the Federal government associated with HHS–RADV program activities, which are covered through the risk adjustment user fees that are charged to issuers. While issuers would indirectly cover these costs through the risk adjustment user fee, we do not anticipate that this policy alone would increase the risk adjustment user fee as the costs are relatively small compared to the entirety of the budget to operate the HHS-operated risk adjustment program. We believe that the benefits from improving the SVA process for validating the IVA results and determining the appropriate audit results to use in error estimation would outweigh the increased costs to the Federal government and better ensure the integrity of the risk adjustment program.

5. Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies (§ 155.220)

As discussed in the preamble to this proposed rule, we address our authority to investigate, engage in compliance reviews of, and take enforcement actions against lead agents of insurance agencies who are engaging in potential misconduct or noncompliant behavior or activities in FFE and SBE–FP States. This would better align our oversight and enforcement approach with how States regulate agencies. This would also ensure enhanced consumer protections from agency-level misconduct or noncompliance facilitated at the agency level, which similarly impacts consumers negatively as misconduct or noncompliance by individual agents, brokers, and web-brokers. This proposal is also designed to reduce consumer harm associated with unauthorized enrollments or bad-

acting agents, brokers, or web-brokers entering incorrect income information on eligibility applications, leading to incorrect APTC calculations. An incorrect APTC amount can result in a consumer having a zero-dollar monthly premium, which may lead to a consumer not knowing they are enrolled or being incorrectly enrolled in an Exchange plan. This generally occurs because the consumer does not receive monthly billing notifications due to the zero-dollar monthly premium. However, once the consumer files their taxes, a reconciliation may reveal the consumer must repay the incorrect APTC amount they were receiving.

This proposal is also designed to reduce consumer harm associated with unauthorized enrollments or unauthorized plan switches which can lead to the consumer receiving a DMI. Upon application submission, certain consumer data is checked against trusted data sources to ensure a match between what is in the application submission and the information HHS receives from the trusted data source(s). If the trusted data source does not have the consumer data or the data is inconsistent with the information provided on the application, a DMI is generated. A non-exhaustive list of DMIs include the Annual Income DMI, Citizenship/Immigration DMI, and American Indian/Alaskan Native Status DMI. Certain DMIs may lead to loss of Exchange coverage, including a Citizenship/Immigration DMI, which occurs when the consumer is unable to verify an eligible citizenship or lawful presence status.

6. Agent and Broker System Suspension Authority (§ 155.220(k))

We believe the impact related to the proposed changes to § 155.220(k)(3) would be positive. The proposed changes would allow HHS to take swift action for misconduct and noncompliance with existing standards and requirements by expanding the bases on which § 155.220(k)(3) system suspensions may be implemented. This proposal would enhance consumer protection and promote program integrity by allowing HHS to immediately suspend an agent's or broker's access to Exchange systems when HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. This would help reduce future consumer harm by allowing HHS to quickly suspend system access for agents or brokers who are engaged in misconduct or noncompliant behavior that impacts Exchange consumers, operations, and systems. This proposal would also increase transparency by informing agents and brokers of the full suite of HHS enforcement actions that may be leveraged in response to noncompliance or misconduct, which may help curb such activities and behaviors. We do not anticipate negative feedback from the entities impacted by this, such as agents and brokers, as these changes are meant to more quickly system suspend bad-acting agents and brokers. This would help build consumer trust in compliant agents and brokers who work with consumers on the FFEs and SBE–FPs.

7. Updating the Model Consent Form (§ 155.220)

We are proposing to update the Model Consent Form to include a section that agents, brokers, and web-brokers assisting with and facilitating enrollment through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs can use to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission in a manner that complies with § 155.220(j)(2)(ii)(A)(1)–(2). We are also proposing to update the Model Consent Form to include scripts agents, brokers, and web-brokers could use when meeting the requirements codified at § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C) via an audio recording.

These proposals would update the optional Model Consent Form that was created as part of the 2024 Payment Notice and adopted on June 18, 2023. The 2024 Payment Notice (88 FR 25890 through 25892) considered the additional time it would take to process and submit each consumer's eligibility application and those assumptions remain and are unchanged. We believe these assumptions remain because we are not changing the regulatory requirements established by the 2024 Payment Notice, and we are not adding requirements with this proposal. The time required to gather the documentation required by the 2024 Payment Notice requirements is already a part of every agent's, broker's, and web-broker's enrollment process. We do not believe the updated Model Consent Form would impose any additional burden on agents, brokers, web-brokers, or consumers; we do not anticipate that the updated Model Consent Form would take any longer to fill out than agent, broker, web-broker, or agency-created forms already being utilized. The use of the proposed Model Consent Form would not be mandatory. Therefore, the proposal would not impart extra time or costs to the assisting agent or broker.

This updated model consent form, if finalized, would provide agents, brokers, and web-brokers with clarity on how to meet the regulatory requirements under § 155.220(j)(2)(ii) and help them comply with this regulation by providing a standardized form they may use to do so. Furthermore, we believe providing a clearly written Model Consent Form would provide more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with § 155.220(j)(2)(ii). The proposed scripts, to the extent they are utilized by agents, brokers, and web-brokers, would help ensure they are following the regulatory requirements when enrolling consumers. We believe this would reduce consumer harm by reducing unauthorized enrollments, which can result in financial harm if a consumer receives an improper APTC amount upon enrollment, and DMIs, which may lead to cancellation of coverage if the DMIs are not resolved in a timely manner. We also believe this proposal would clarify and simplify how regulated entities can meet regulatory requirements.

We seek comment on these assumptions.

8. Requirement for Notification of Tax Filers and Consumers Who Have Failed To File and Reconcile APTC for Two Consecutive Tax Years (§ 155.305)

We anticipate a small financial impact related to our proposed changes at § 155.305(f)(4)(i)(A)(1)–(2). Prior to pausing the FTR process during the COVID–19 public health emergency, Exchanges provided notice to enrollees or their tax filers (or both) who were identified as at risk of losing their APTC due to their failure to file their Federal income taxes and reconcile their APTC using Form 8962 prior to the FTR Recheck process. The 2025 Payment Notice codified the requirement to send notices in the first tax year a tax filer was identified as having FTR status. This proposal would require sending either direct or indirect notices to tax filers and their enrollees when the tax filer is identified as having FTR status for a second consecutive tax year, which

we estimated in the 2024 Payment Notice to represent 20 percent of the total FTR population. We estimate the cost for Exchanges on the Federal platform to provide direct notices that protect Federal tax information to tax filers would be approximately $134,000 yearly for fiscal years 2025 through 2029, although there is potential for future growth in the outyears based on increases in the cost of postage and inflation in future years. However, the Departments are not publishing specific future contract estimates in this rule in response to commenters' requests for more detail on estimated expenditures of Federal notice printing activities and the data underlying those estimates because publishing those contract estimates could undermine future contract procurements. For example, if the Department was to publish the projected future cost of the contracts used to provide print notifications, the Federal government would be meaningfully disadvantaged in future contract negotiations related to Federal notice printing activities, as bidders would know how much the Department anticipates such a future contract being worth. Although current contract awards are published and publicly available,[268] these award amounts do not necessarily reflect the future value of the contract, as there may be future changes in policy and operations and the scope of the work. Our proposed regulations, if finalized, would give flexibility to Exchanges to choose to send the required notices to enrollees or tax filers, or both. Given the uncertainty about how State Exchanges would choose to provide notices to their enrollees as well as the proportion of enrollees on State Exchanges who fail to file their Federal income taxes and reconcile their APTC for two consecutive tax years, we are unable to provide exact estimates of the cost of providing these notices. We believe that if State Exchanges chose to provide direct mailing notices, the approximate cost could be $0.84 per notice for FY 2025 based on the cost for the Exchanges on the Federal platform to send an average notice and would likely grow with postage and inflation costs in future years. We anticipate approximately 38,000 total notices across State Exchanges based on historical FTR data from the Exchanges on the Federal platform, and so in total, the estimated cost to State Exchanges to send these notices would be approximately $31,920 yearly for fiscal years 2025–2029. However, we think this is likely an overestimate based on conversations with interested parties because many State Exchanges may prefer to provide indirect notices that can be emailed, which would substantially reduce costs to the State Exchanges. There could be some cost related to creation of the notice, but State Exchanges could also choose to use either the language that Exchanges on the Federal platform already use or the language previously used in FTR notices.

We seek comments on this proposal, including regarding additional costs, burdens, and benefits to issuers, consumers, and Exchanges as a result of this proposal.

9. Timeliness Standard for State Exchanges To Review and Resolve Enrollment Data Inaccuracies (§ 155.400(d)(1))

We propose to add § 155.400(d)(1) to codify HHS' guidance document titled, ''Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges Frequently Asked Questions,'' [269] which provides that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange (hereinafter referred to as ''State Exchange issuer'') that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuers' enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS. This proposed policy aligns with the existing requirement at § 155.400(d) that a State Exchange must reconcile enrollment information with issuers and HHS no less than on a monthly basis. It also provides certainty for State Exchange issuers by providing a timeline for State Exchanges to act upon an enrollment data inaccuracy submitted to the State Exchange by a State Exchange issuer that meets the requirements at § 156.1210(a)–(c).

We do not believe that the proposed amendment would impose substantial additional costs to HHS, State Exchanges, or State Exchanges issuers beyond the costs that are already accounted for as part of the existing issuers' enrollment data inaccuracies description process and existing State Exchange enrollment data reconciliation requirements. The existing process already requires State Exchange issuers to submit enrollment inaccuracies and the State Exchanges to resolve those inaccuracies and reconcile enrollment information with both State Issuers and HHS no less than on a monthly basis. We have no reason to believe that codifying a timeliness standard would increase burden.

Furthermore, this proposal to codify a timeliness standard for resolution of enrollment data inaccuracies would clarify to issuers in State Exchanges the process for timely reviewing and resolving enrollment data inaccuracies and would ensure the accurate and timely payment of APTCs as this enrollment data is the basis of APTC payments to State Exchange issuers in the automated PBP system.

Therefore, we anticipate that this proposal would streamline the existing issuers' enrollment data inaccuracies process and benefit consumers by ensuring accurate payment of APTCs.

We seek comment on these impact estimates and assumptions.

10. Establishment of Optional Fixed-Dollar Premium Payment Threshold and Total Premium Threshold (§ 155.400(g))

We anticipate that the proposal to allow issuers to implement a fixed-dollar premium payment threshold, adjusted for inflation, would benefit enrollees who may otherwise have been unable to maintain enrollment due to owing *de minimis* amounts of premium. The proposal would likely be especially beneficial to enrollees who are low income, who might be disproportionately impacted by disruptions in coverage. In addition, we believe that issuers that choose to implement a fixed-dollar premium payment threshold would benefit by being able to continue enrollment for enrollees who owe small amounts of premium. We anticipate that there would be some costs associated with implementing a fixed-dollar threshold for those issuers that chose to do so, as well as State Exchanges that chose to allow issuers to do so. Since the proposal would be optional for issuers to adopt, and some may choose not to adopt a payment threshold at all, it is challenging to quantify the impact on APTC payments. However, assuming a fixed-dollar threshold of $5 or less, based on PY 2023 counts of 79,612 QHP policies terminated for non-payment where the enrollee had a member

[268] Available at *sam.gov*.

[269] CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf*.

responsibility amount of $0.01–$5.00, with an average monthly APTC of $604.78 per enrollee (for PY 2023), we estimate that this at most would result in $481,477,453.60 in APTC payments for 10 months that excludes the binder payment and first month of the grace period (which the issuer already received APTC for and wouldn't have to return) that issuers would retain, rather than being returned to the Federal government.[270] We seek comment on quantifying a lower limit, and whether there are additional costs for other interested parties that have not been considered here.

11. General Eligibility Appeals Requirements (§ 155.505)

This proposed change would allow application filers to file appeals through the HHS appeals entity or a State Exchange appeals entity on behalf of applicants and enrollees on their Exchange application, streamlining the appeals process and ensuring operational consistency between the FFEs and appeals entities. We do not anticipate any financial impact related to our proposed change at § 155.505(b).

12. Proposed Amendments to Certification Standards for QHPs, Request for the Reconsideration of Denial of Certification, and Non-Certification and Decertification of QHPs (§§ 155.1000 and 155.1090)

We propose to amend § 155.1000 by clarifying that an Exchange may deny certification to any plan that does not meet the general certification criteria at § 155.1000 and amend § 155.1090 with refinements to the standards for the request for the reconsideration of a denial of certification specific to the FFEs. We anticipate no appreciable changes in impact because of these proposals. We expect that the FFE would deny certification to one or fewer certification applications on average each year, so we expect the number of affected entities to be small. In addition, the proposed revisions to §§ 155.1000 and 155.1090 do not substantively alter the responsibilities of affected issuers or the content of reconsideration requests. As a result, there is no material impact on regulated entities because of these proposals.

13. General Program Integrity and Oversight Requirements (§ 155.1200)

As part of § 155.1200, we intend to increase transparency in Exchanges by publishing annual State Exchange and SBE–FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment (OE) data reports. We anticipate no appreciable change in impact with this proposal since this data is already collected through the Blueprint application (OMB Control Number: 0938–1172), SMART (OMB Control Number: 0938–1244), and Enrollment Metrics PRA (OMB Control Number: 0938–1119). We expect that this proposal would increase the public's understanding of State Exchanges, promote program improvements, and better evaluate Exchange quality.

14. FFE and SBE–FP User Fee Rates for the 2026 Benefit Year (§ 156.50)

We propose an FFE user fee rate of 2.5 percent of monthly premiums for the 2026 benefit year, which is greater than the FFE user fee rate finalized in the 2025 Payment Notice (89 FR 26336 through 26338) of 1.5 percent of total monthly premiums. We also propose an SBE–FP user fee rate of 2.0 percent for the 2026 benefit year, which is greater than the SBE–FP user fee rate finalized in the 2025 Payment Notice of 1.2 percent of total monthly premiums. As a result, we estimate an increase in FFE and SBE–FP user fee transfers from issuers to the Federal government of $644 million for benefit year 2026 compared to if the user fee level from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE–FP user fee transfers from issuers to the Federal government of $849 million in 2027, $852 million in 2028, and $854 million in 2029 if the proposed 2026 benefit year user fee level were maintained in subsequent years.

We anticipate that these proposed user fee rates would have upward pressure on premiums compared to the 2025 benefit year. We believe that increasing the user fee rates from the 2025 Payment Notice would provide financial stability to the Exchanges on the Federal platform, ensure continuity of special benefits to issuers, and access to QHP plans for enrollees.

We also propose alternate user fee rate ranges if Congress extends the current or a higher level of enhanced PTC subsidies for the 2026 benefit year by March 31, 2025. We recognize that the expiration of the enhanced PTC subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and despite this uncertainty, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the operations of the FFEs. Therefore, if the enhanced PTC subsidies as currently enacted or higher are extended through the 2026 benefit year by March 31, 2025, we propose a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE–FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule. As a result, if we finalize user fee rates from these ranges, we estimate an increase in FFE and SBE–FP user fee transfers from issuers to the Federal government of between $425 million to $690 million for benefit year 2026 compared to if the user fee level from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE–FP user fee transfers from issuers to the Federal government of between $585 million to $950 million in 2027, $607 million to $985 million in 2028, and $629 million to $1.021 billion in 2029 if the alternate proposed 2026 benefit year user fee level were maintained in subsequent years. We seek comment on whether March 31, 2025, provides issuers sufficient time to request rates and for States to review rate requests.

15. Amendments to AV Calculator Update Methodology (§ 156.135)

This approach to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator, resulting in an earlier release of the final AV Calculator for a given plan year, would benefit both issuers and States. Issuers have previously provided feedback that HHS should strive to release the final version of the AV Calculator sooner, and this approach addresses such requests. In addition, States could benefit from an earlier release of the final version of the AV Calculator to ensure their EHB-benchmark plans comply with EHB requirements, and States that design their own standardized plan options could benefit from an earlier release to ensure they satisfy the AV de minimis ranges. This approach would have no impact on consumers.

We seek comment on these impact estimates and assumptions.

16. Standardized Plan Options (§ 156.201)

We are proposing minor updates to the standardized plan options for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level. We believe maintaining a high degree of continuity in the approach to standardized plan options year over year minimizes the risk of disruption for interested parties, including issuers,

[270] See CMS (2024) *Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average. https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf.*

agents, brokers, States, and enrollees. We continue to believe that making major departures from the approach to standardized plan options set forth in the 2023, 2024, and 2025 Payment Notices could result in changes that may cause undue burden for interested parties. For example, if the standardized plan options we create vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost sharing for services they rely upon differs substantially from the previous year. Ultimately, we believe consistency in standardized plan options is important to allow both issuers and enrollees to become accustomed to these plan designs.

Thus, like the approach taken in the 2023, 2024, and 2025 Payment Notices, we are proposing standardized plan options that continue to resemble the most popular QHP offerings that millions of consumers are already enrolled in. As such, these proposed standardized plan options are based on updated cost sharing and enrollment data to ensure that these plans continue to reflect the most popular offerings in the Exchanges. By proposing an approach to standardized plan options like that taken in the 2023, 2024, and 2025 Payment Notices, issuers would continue to be able to utilize many existing benefit packages, networks, and formularies, including those paired with standardized plan options for PY 2025. Further, issuers would continue to not be required to extend plan offerings beyond their existing service areas.

Furthermore, as discussed earlier in the preamble, we intend to continue to differentially display standardized plan options on *HealthCare.gov* per § 155.205(b)(1). Since we intend to continue to assume responsibility for differentially displaying standardized plan options on *HealthCare.gov,* FFE and SBE–FP issuers would continue to not be subject to this burden. In addition, as noted in the preamble, we intend to continue enforcement of the standardized plan option display requirements for approved web-brokers and QHP issuers using a direct enrollment pathway to facilitate enrollment through an FFE or SBE–FP—the Classic DE and EDE Pathways—at §§ 155.220(c)(3)(i)(H) and 156.265(b)(3)(iv), respectively. We believe that continuing the enforcement of these differential display requirements would not impose a significant burden on these entities or require major modification of their non-Exchange websites, especially since the bulk of this burden was previously imposed in the 2018 Payment Notice, which finalized the standardized plan option differential display requirements, or during the PY 2023 open enrollment period, when enforcement of these requirements resumed.

Finally, since we intend to continue to allow approved web-brokers and QHP issuers to submit requests to deviate from the manner in which standardized plan options are differentially displayed on *HealthCare.gov,* the burden on these entities would continue to be minimal. We intend to continue providing access to information on standardized plan options to web-brokers through the Health Insurance Marketplace PUFs and QHP Landscape file to further minimize burden by ensuring that affected entities have timely access to accurate and helpful information on standardized plan option requirements, including those related to the differential display of these plans.

We do not anticipate that the proposed modification at § 156.201(c) that would require an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, networks, and/or formularies would have a significant impact on issuers. This is because most issuers have not offered multiple standardized plan options within the same product network type, metal level, and service area since these requirements were introduced in PY 2023. In fact, current QHP certification submission data indicates that only three issuers intend to offer multiple standardized plan options within the same product network type, metal level, and service area in PY 2025.

However, we acknowledge that those issuers that do offer multiple standardized plan options in the same product network type, metal level, and service area would either have to modify certain offerings (such as by modifying included benefits, provider networks, and/or formularies) or choose to discontinue certain plans to the extent they are not meaningfully different. That said, given that issuers would retain the discretion to choose between modifying or discontinuing plans, and given that making these modifications to plans are a routine part of the annual plan design process, we do not anticipate significant burden for affected issuers related to this proposed requirement.

We seek comment on these impact estimates and assumptions.

17. Non-Standardized Plan Option Limits (§ 156.202)

We propose to amend § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since the introduction of these requirements to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage categories under the non-standardized plan option limit at § 156.202(b) in accordance with § 156.202(c)(1) through (3).

In particular, we propose to amend § 156.202(b) to properly distinguish between adult dental benefit coverage at § 156.202(c)(1) and pediatric dental benefit coverage at § 156.202(c)(2), such that an issuer offering QHPs in an FFE or SBE–FP, for PY 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), in any service area.

We propose a similar conforming amendment to § 156.202(d), such that for PY 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage, and service area.

We propose these modifications to align the regulation text with the existing flexibility that issuers have been operationally permitted since the non-standardized plan option limit was introduced in the 2024 Payment

Notice.[271] Given that issuers have had this flexibility since the non-standardized plan option limit was first introduced PY 2024, we do not any anticipate any impact on relevant interested parties.

We seek comment on these impact estimates and assumptions.

18. Essential Community Provider Certification Review for States Performing Plan Management Functions (§ 156.235)

This proposal to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions beginning in PY 2026 would not have a significant financial impact on the Federal government. HHS continues to perform ECP certification reviews for plans in the FFEs, so the financial burden to conduct the certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions using the existing data infrastructure is a marginal increase within the annual programming for QHP certifications. For PY 2025, HHS would use MPMS for ECP reviews for plans seeking QHP certification in FFEs, and HHS has all the necessary data infrastructure and operational processes to conduct reviews for States performing plan management functions for PY 2026 as proposed. While the Federal government would undertake additional administrative work to review the ECP data from QHP certification applications submitted by issuers seeking certification of their plans as QHPs in FFEs in States performing plan management functions, the transfer of administrative impact from the State that had been performing these reviews to the Federal government is marginal, as the Federal government already has in place processes and procedures to conduct the ECP certification reviews. HHS would continue ECP QHP certification reviews in all other FFE States.

This proposal would reduce the administrative burden for these States as they would no longer be responsible for ECP data review. We estimate a cost savings of $157,052.70 per State annually for each of the 12 FFE States performing plan management functions in PY 2026.[272] This is calculated by taking the mean hourly wage for a compliance officer of $38.55, according to the Occupational Employment and Wage Statistics,[273] and adding 100 percent fringe benefits to total $77.10. We estimate the operations and maintenance costs for the ECP QHP data collection and the QHP data collection support to equal 485 hours for 4.2 full-time equivalents,[274] totaling $157,052.70. The total cost across the 12 FFE States performing plan management functions would be $1,884,632.40. This cost associated with ECP enforcement/compliance reviews would be transferred from the States performing plan management functions to the Federal government. We further estimate an annual cost of $8,155 associated with ECP compliance reviews that would be transferred from the FFEs in States performing plan management functions to the Federal government based on current contract costs.

Further, this proposal should not lead to increased burden for issuers in the FFE in States performing plan management functions as they would still have to submit ECP data to HHS regardless of whether it is the State or HHS conducting the QHP certification review. In previous years, these issuers were required to submit ECP data to HHS via the SERFF binders, whereas these issuers are now required to submit their ECP data to HHS in MPMS beginning with the PY 2025 QHP application submission season, making it now possible for HHS to begin reviewing these ECP data going forward.

In addition, this proposal would not financially impact providers on the HHS ECP list.[275] There is no fee to be included in the HHS ECP list, and the administrative burden to complete the petition continues to be the same. The proposal would support consumer access to vitally important medical and dental services, enhancing health equity for low-income and medically underserved consumers.

We seek comment on these impact estimates and assumptions.

19. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

We propose to amend § 156.1220(a)(2) to codify a materiality threshold for when HHS would rerun HHS–RADV results in response to a successful HHS–RADV appeal. We believe that this proposal supports providing stability for issuers that participate in risk adjustment because it limits the potential for issuers to reopen their books for small changes to their State transfers because of a successful HHS–RADV appeal. This proposal would avoid situations where HHS is required to rerun HHS–RADV results, and for all issuers to reopen their books, when the impact for the filer of a successful HHS–RADV appeal is less than $10,000. Because this approach is limited to small dollar amounts, we do not believe that the proposal would materially impact issuers or their premiums and it would provide stability to issuers by limiting the situations where their books would need to be reopened. We believe that this proposal, when applicable, would reduce Federal costs by an estimated $75,000 due to the estimated 575 hours of contractor work. We also believe that this proposal, when applicable, would reduce Federal costs through a decrease in HHS staff work hours. These HHS staff are funded by the risk adjustment user fee, therefore there is no cost impact. Rerunning HHS–RADV results requires HHS to recalculate all national metrics, reissue all issuers' error rate results, and then apply all of those revised error rates to State transfers for the applicable benefit year before going through the process to net, invoice, collect, and redistribute the changes to the HHS–RADV adjustments to State transfers.

20. Medical Loss Ratio (§§ 158.103, 158.140, 158.240)

We propose to add a definition of ''qualifying issuer'' to § 158.103, amend § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year, amend § 158.240(c) to add an illustrative example of how qualifying issuers would determine the amount of rebate owed to each enrollee, and make a conforming amendment to § 158.240(c) to clarify that the current illustrative example in paragraph (c)(2)

[271] CMS. (2024, April 10). *2025 Final Letter to Issuers in the Federally-facilitated Exchanges. https://www.cms.gov/files/document/2025-letter-issuers.pdf.*

[272] Twelve FFEs operate in States performing plan management functions for PY 2026: Delaware, Hawaii, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

[273] Occupational Employment and Wage Statistics from the US Bureau of Labor Statistics for job code 13–1041 Compliance Officer from *https://www.bls.gov/oes/current/oes131041.htm.*

[274] We estimated 485 hours for 4.2 full time equivalent similar to the administrative burden cost for the Federal government as indicated in cost estimate of the Supporting Statement for Continuation of Data Collection to Support QHP Certification and other Financial Management and Exchange Operations OMB control number: 0938–1187.

[275] A non-exhaustive list of available ECPs that primarily serve low-income and medically underserved populations which can be counted toward an issuer's satisfaction of the ECP standard as part of the issuer's QHP application.

would apply to issuers that are not qualifying issuers. These proposals, which would extend only to issuers whose ratio of net payments related to the risk adjustment program under section 1343 of the ACA, to earned premiums prior to accounting for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs (as described in § 158.130(b)(5)) in a relevant State and market is greater or equal to 50 percent, would result in transfers to such issuers from their enrollees in the form of lower rebates or higher premiums. Based on MLR data for 2022, these proposals would reduce rebates paid by issuers to consumers or increase premiums collected by issuers from consumers by a total of approximately $20 million per year.

Under the alternative approach we are considering, in which the proposed amendments to § 158.140(b)(4)(ii) and § 158.240(c) would extend to all issuers subject to the risk adjustment program, based on 2022 MLR data, these proposed amendments would reduce rebates paid by issuers to consumers or increase premiums collected by issuers from consumers by a net total of approximately $164 million per year.

We seek comment on these impact estimates and assumptions.

21. Regulatory Review Cost Estimation

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 a range of between the total number of unique commenters on last year's proposed rule (251) and the total number of page views on last year's proposed rule (about 10,000) will include the actual number of reviewers of this proposed rule. We therefore use an average number of approximately 5,125 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 page viewers did not actually read the proposed rule. For these reasons, we believe that the average of the number of commenters and number of page viewers on last year's proposed rule would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We 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 55 percent of the rule (an average of the range from 10 percent to 100 percent of the rule). We seek comments on this assumption.

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 $106.42 per hour, including overhead and fringe benefits.[276] Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 3.6 hours for the staff to review 55 percent of this proposed rule. For each entity that reviews the rule, the estimated cost is $383.11 (3.6 hours × $106.42 per hour). Therefore, we estimate that the total cost of reviewing this regulation is approximately $1,963,438.75 ($383.11 per reviewer × 5,125 reviewers).

D. Regulatory Alternatives Considered

Under § 153.630(b), we propose to exclude enrollees without HCCs, remove the FPC, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to HHS–RADV data beginning with the 2025 benefit year of HHS–RADV.

The proposed IVA sampling methodology would use the most recent 3 consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin to calculate a national variance of net risk score error to calculate each issuer's standard deviation of risk score error used in the Neyman allocation formula, whereas the current IVA sampling methodology relies on MA–RADV data to calculate this national variance of net risk score error.[277] When investigating the impact of switching the Neyman allocation data source to the most recent 3 consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin, we considered creating an issuer-specific variance of net risk score error to calculate each issuer's standard deviation of risk score error used in the Neyman allocation formula. However, it would not be possible to calculate an issuer-specific variance of net risk score error for all issuers participating in a given benefit year of HHS–RADV as some issuers would not have 3 consecutive years of HHS–RADV data. As explained earlier in this preamble, these issuers would have to rely on less years of HHS–RADV data under an issuer-specific calculation, meaning significantly fewer data points compared to other issuers that participated in all years, which could result in large variations in IVA sample stratum size and increased uncertainty in HHS–RADV. Therefore, we propose to continue calculating each issuer's standard deviation of risk score error using a national variance of net risk score error, but to use a 3-year rolling window of HHS–RADV data rather than the MA–RADV data as the source data for the Neyman allocation.

We considered proposing to replace the source of the Neyman allocation data while continuing to include enrollees without HCCs in IVA sampling and retaining the FPC.[278] However, this would result in sampling a greater proportion of enrollees without HCCs, who do not have risk scores to adjust when calculating issuers' error rates during HHS–RADV. In addition, keeping the FPC while excluding enrollees without HCCs from IVA sampling and replacing the source data for the Neyman allocation with available HHS–RADV data would lead to a dramatic increase in the number of issuers subject to the FPC and therefore decrease the total count of Super HCCs in issuers' IVA samples. For example, we estimate that the average Super HCC count for issuers currently subject to the FPC would decrease by 26 percent by retaining the FPC, which would increase the proportion of issuers that fail to meet the 30 Super HCC constraint in HHS–RADV.[279] In contrast, removing the FPC would increase the average Super HCC count for these same issuers by 30 percent, which would improve issuers' probability of meeting the 30 Super HCC constraint. Overall, our analyses found that making these modifications in combination would lead to the greater improvements in

[276] U.S. Bureau of Labor Statistics. (2024, April 9). *Occupational Employment and Wage Statistics. https://www.bls.gov/oes/current/oes_nat.htm.*

[277] As noted in the preamble of this rule, a new benefit year of HHS–RADV activities generally begins in the spring when issuers can start selecting their IVA entity and IVA entities can start electing to participate in HHS–RADV for that benefit year. We would use data from the 3 most recent consecutive years of HHS–RADV where results have been released. See, for example, the 2023 Benefit Year HHS–RADV Activities Timeline for the general structure of the HHS–RADV timeline. *https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.*

[278] As explained in the preamble of this rule, enrollees without HCCs include stratum 10 enrollees that do not have HCCs nor RXCs and RXC-only enrollees in strata 1 through 3.

[279] As noted earlier in this preamble, this estimate is based on the combined impact of all proposed changes to the IVA sampling methodology.

sampling precision and would allow more than 95 percent of issuers to pass the 10 percent sampling precision target at a two-sided 95 percent confidence level.

We also considered only excluding stratum 10 enrollees from the IVA sampling methodology and retaining RXC-only enrollees in strata 1 through 3. However, we believe removing all enrollees without HCCs (both stratum 10 enrollees and RXC-only enrollees) is the preferred approach so issuers and IVA Entities are not spending resources on enrollees who do not have risk scores to adjust when calculating issuers' error rates during HHS–RADV. In addition, our analysis reveals the greatest improvements in precision and greatest decreases in the average medical records reviewed per enrollee, and therefore the greatest decreases in issuer and IVA Entity burden, when excluding RXC-only enrollees and stratum 10 enrollees from the IVA sampling methodology.

As an alternative respect to the SVA pairwise means test proposal we considered only changing the pairwise means testing procedure from the 95 percent confidence interval paired t-test to the 90 percent confidence interval bootstrapped test without increasing the initial SVA subsample size to 24. However, our analysis found that maintaining an initial SVA subsample size of 12 under the bootstrapping methodology did not achieve an optimal target false negative rate of approximately 20 percent at various effect sizes. Therefore, we are proposing to modify the pairwise means test to use a 90 percent confidence interval bootstrapping methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.[280]

[280] A standard IVA sample size is 200 enrollees, and it applies to the majority of issuers of risk adjustment covered plans. CMS calculates a smaller IVA sample sizes for issuers for smaller populations by using a Finite Population Correction (FPC) factor. All issuers are subject to the same SVA subsample sizes, but the maximum SVA subsample for pairwise testing is one half of the issuer's IVA sample size. As discussed in section II.B.5.a., we are proposing changes to the IVA sampling methodology that would exclude enrollees without HCCs from IVA sampling and remove the FPC factor such that all IVA samples will consist of 200 enrollees with HCCs or the issuer's total EDGE population of enrollees with HCCs if they have less than 200 enrollees with HCCs beginning with the 2025 benefit year of HHS–RADV. Under this policy, the SVA subsample size expansion for issuers with less than 200 enrollees with HCCs would continue to follow the standard SVA subsample sizes with a maximum SVA subsample for pairwise testing equal to one half of the issuer's IVA sample size. If the issuer fails at the maximum SVA subsample size for pairwise testing, a precision analysis if performed to determine whether the SVA audit results from that maximum SVA subsample size can be used in error estimation or if the SVA sample needs to expand to the full IVA sample.

We considered taking no action regarding the proposed changes at § 155.305(f)(4)(ii) and instead relying on the guidance released by CMS to inform Exchanges of noticing best practices as was previously done, but instead decided to codify this as a requirement to ensure that tax filers or their enrollees receive multiple educational notices regarding the requirement to file their Federal income taxes and reconcile their APTC.

We considered taking no action regarding our proposal to modify § 155.400(g) to allow issuers to adopt a fixed-dollar premium payment threshold or a gross premium-based percentage payment threshold. However, the proposal would provide important flexibility to issuers that wish to allow enrollees who owe de minimis amounts of premium to maintain their enrollment. This flexibility is limited under current regulation, and as a result enrollees who owe small amounts of premium are sometimes unable to remain enrolled. We are soliciting feedback from interested parties on whether a fixed-dollar threshold, or a percentage threshold based on gross premium, would better meet our goal of providing flexibility to issuers to allow enrollees to avoid triggering a grace period and termination of enrollment through the Exchange for owing small amounts of premium. For the fixed-dollar premium payment threshold, we are also considering whether to implement a $5 or $10 cap on the fixed-dollar threshold because while we believe the $5 cap is sufficient to help many enrollees avoid termination, CMS data on non-payment terminations also indicate that there are a considerable number of policies that were terminated in PY2023 with a member responsibility amount of $10 or less. We are soliciting feedback from interested parties in order to determine what the appropriate cap should be on the fixed-dollar threshold. We also considered keeping the existing net premium-based threshold at a ''reasonable'' limit, which we recommended to be 95 percent or higher, but are proposing to specifically define the threshold at 95 percent or higher, in order to provide clarity for issuers and Exchanges. We also considered whether it would be administratively feasible to allow issuers to adopt both a fixed-dollar and percentage-based threshold but restricted issuers to choosing one threshold method. We are soliciting feedback from interested parties on whether we should allow this flexibility.

For the proposed 2026 benefit year FFE and SBE–FP user fees, we considered only proposing one FFE user fee rate and one SBE–FP user fee rate as we have done in previous years. However, we recognize that the expiration of the enhanced PTC subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and despite this uncertainty, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the operations of the FFEs. Therefore, we are proposing an FFE user fee rate of 2.5 percent of monthly premiums for the 2026 benefit year, which is greater than the FFE user fee rate finalized in the 2025 Payment Notice (89 FR 26336 through 26338) of 1.5 percent of total monthly premiums, and if the enhanced PTC subsidies as currently enacted or at a higher level are extended through the 2026 benefit year by March 31, 2025, we are also proposing a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and a 2026 benefit year SBE–FP user fee rate range between 1.4 and 1.8 of total monthly premiums, with each of these ranges to be set at a single rate in the final rule.

We considered taking no action regarding our proposal to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions under § 156.235. Not conducting reviews as proposed would maintain current certification operations for issuers in FFE States that perform plan management functions and continue to provide States with the ability to use a similar approach to Federal ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs. However, due to the implementation of the MPMS and enhancement of the ECP user interface, issuers seeking QHP certification in FFEs, including States performing plan management functions, can now submit ECP data to HHS for data integrity of the Federal platform regardless of whether it is the State or HHS conducting the review.

We propose to amend § 156.1220(a)(2) to codify when HHS would take action in response to a successful HHS–RADV appeal. We considered several ways to design the new materiality threshold to rerun HHS–RADV results. For example, we considered setting the second materiality threshold to rerun HHS–RADV results to include a percentage of

HHS–RADV adjustments and applying a 1 percent test to align with the EDGE materiality threshold in § 153.710(e). However, considering that the HHS–RADV adjustments to State risk adjustment transfer charges and State risk adjustment transfer payments are orders of magnitude smaller than those of the initial State risk adjustment transfer amounts, we were concerned that we would see situations where 1 percent of the applicable payment or charge could be as little as $10 based on our experience running HHS–RADV for the past few years. Specifically, we believe that structuring the threshold, as proposed, to the financial impact of the filer and applying an equal to or greater than $10,000 amount would balance the need for ensuring that HHS–RADV results are accurate with the desire for ensuring that changes in HHS–RADV results actually have a meaningful financial impact. This proposed new materiality threshold to rerun HHS–RADV results takes into consideration the existing materiality threshold for filing a request for reconsideration, which applies to a number of different program appeals. To remain consistent with this existing threshold and recognizing that HHS–RADV adjustments are significantly smaller in magnitude than risk adjustment transfers, we believe that $10,000 is a reasonable threshold, but we solicit comment on this dollar amount and whether it should be higher or lower or whether we should consider including an inflation adjustment rate to this amount. This new proposed materiality threshold to rerun HHS–RADV results also considers the fact that it costs HHS approximately $75,000 to rerun HHS–RADV and re-release results. Reducing the number of times HHS–RADV needs to be rerun and HHS–RADV adjustments need to be re-released also helps maintain the stability of the market, as there are fewer instances of adjustments after the initial release of HHS–RADV adjustments.

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that small businesses, nonprofit organizations, and small governmental jurisdictions are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). We do not anticipate that providers would be directly impacted by the proposals in this proposed rule. Individuals and States are not included in the definition of a small entity. The proposals in this proposed rule would affect Exchanges and QHP issuers.

For purposes of the RFA, we believe that health insurance issuers would be classified under the NAICS code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $47 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard will be $44.5 million or less.[281] 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) would fall below these size thresholds. Based on data from MLR annual report submissions for the 2022 MLR reporting year, approximately 87 out of 487 issuers of health insurance coverage nationwide had total premium revenue of $47 million or less.[282] This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 76 percent of these small issuers 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 $47 million. Therefore, although it is likely that fewer than 87 issuers are considered small entities, for the purposes of this analysis, we assume 87 small issuers would be impacted by this proposed rule.

The proposed policies that would result in an increased burden to small entities are described below.

We propose to update the IVA sampling methodology, including the proposed removal of enrollees without HCCs (including RXC-only enrollees), removing the FPC, and replacing the source of the Neyman allocation data with the most recent 3 years of consecutive HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin, beginning with benefit year 2025 HHS–RADV. The total cost savings associated with this proposal would be approximately $79,121.92 per issuer audited per year. For more details, please refer to the Regulatory Impact Analysis section associated with this policy in this proposed rule.

We propose to add a definition of ''qualifying issuer'' and to no longer require such issuers to adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes. This proposal would reduce rebates paid by these issuers to consumers or increase premiums collected by these issuers from consumers by approximately $20 million annually. The cost savings per issuer would therefore be approximately $41,067.76.[283] For more details, please refer to the Regulatory Impact Analysis section associated with this policy in this proposed rule.

Thus, the per-entity estimated annual cost savings for small issuers is $120,189.68, and the total estimated annual cost savings for small issuers is $10,456,502.16. See tables 18 and 19.

TABLE 18: Detailed Annual Costs for Small Entities

Description of Cost	Annual Cost per Small Entity
HHS-RADV IVA changes	-$79,121.92
MLR changes	-$41,067.76
Total	-$120,189.68

[281] SBA. (n.d.). *Table of size standards. https://www.sba.gov/document/support--table-size-standards.*

[282] CMS. (n.d.). *Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[283] $20 million/487 issuers participating in the MLR program = approximately $41,076.67.

TABLE 19: Aggregate Annual Costs for Small Entities

Affected Entity	Affected Small Entities	Annual Cost per Entity	Aggregate Annual Cost for Small Entities
Issuer	87	-$120,189.68	-$10,456,502.16

We seek comment on this analysis and seek information on the number of small issuers that may be affected by the provisions in these proposed rules.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule, given that the annual per-entity cost savings of $120,189.68 per small issuer represents approximately 0.06 percent of the average annual receipts for a small issuer.[284] Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For the purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that this rule will not affect small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. Although we have not been able to quantify all costs, we expect that the combined impact on State, local, or Tribal governments and the private sector does not meet the UMRA definition of unfunded mandate.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, we have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC, and consulting with State insurance officials on an individual basis.

While developing this rule, we attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of Executive Order 13132.

Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For States that elected previously to operate an Exchange, those States had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In our view, while this proposed rule will not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to potential direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, the proposal to conduct ECP certification reviews for States performing plan management functions effective beginning in plan year 2026 may have Federalism implications, given that HHS has not conducted Federal ECP certification reviews for States performing plan management functions since the 2015 plan year. However, these Federalism implications may be balanced by enabling HHS to align standards in these States with Federal review standards, and thereby increasing consumer access in these States and improving efficiency of the QHP certification process. Additionally, we do not believe that the proposed amendment to codify the timeliness guidance for State Exchanges to review and resolve the State Exchange issuers enrollment data inaccuracies within 60 calendar days would have significant Federalism implications because this proposal is merely codifying a timeline for an existing data submission requirement.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 30, 2024.

List of Subjects

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs—health, Grants

[284] United States Census Bureau (2020, March). *2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size. https://www.census.gov/data/tables/2020/econ/susb/2020-susb-annual.html.*

administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 1. 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.

■ 2. Section 155.220 is amended by revising paragraph (k)(3) to read as follows:

§ 155.220 Ability of States to permit agents, brokers, web-brokers, and agencies to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(k) * * *

(3) HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under paragraph (j)(2)(i), (ii), or (iii) of this section and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.

* * * * *

■ 3. Section 155.305 is amended by adding paragraph (f)(4)(ii) to read as follows:

§ 155.305 Eligibility standards.

* * * * *

(f) * * *

(4) * * *

(ii) If HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that APTC payments were made on behalf of either the tax filer or their spouse, if the tax filer is a married couple, for 2 consecutive tax years for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i), and the tax filer or the tax filer's spouse did not comply with the requirement to file an income tax return for both years as required by 26 U.S.C. 6011, 6012, and their implementing regulations and reconcile APTC for that period (''file and reconcile''), the Exchange must:

(A) Send a direct notification to the tax filer, consistent with the standards applicable to the protection of Federal Tax Information, that explicitly informs the tax filer that the Exchange has determined that the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file their Federal income taxes and reconcile APTC, and educate the tax filer of the need to file and reconcile or risk being determined ineligible for APTC after 2 consecutive years of failing to file and reconcile; or

(B) Send an indirect notification to either the tax filer or their enrollee, that informs the tax filer or enrollee that they may be at risk of being determined ineligible for APTC after 2 years of failing to file and reconcile. These notices must educate tax filers or their enrollees on the requirement to file and reconcile, while not directly stating that the Internal Revenue Service indicates the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file and reconcile.

* * * * *

■ 4. Section 155.400 is amended by adding paragraph (d)(1) and a reserved paragraph (d)(2) and revising paragraph (g) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(d) * * *

(1) *Timeliness standard for State Exchanges to review, resolve, and report data inaccuracies submitted by a State Exchange issuer.* Within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in the State Exchange that includes a description of a data inaccuracy in accordance with § 156.1210 and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuer's data inaccuracies and submit to HHS a description of the resolution of the inaccuracies in a format and manner specified by HHS.

(2) [Reserved]

* * * * *

(g) *Premium payment threshold.* Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal platform will, allow issuers to implement either a percentage-based premium payment threshold policy (which can be based on either the net premium after application of advance payments of the premium tax credit or gross premium) or a fixed-dollar premium payment threshold policy, provided that the threshold and policy is applied in a uniform manner to all applicants and enrollees.

(1) Under a net premium percentage-based premium payment threshold policy, issuers can consider applicants or enrollees to have paid all amounts due for the following purposes, if the applicants or enrollees pay an amount sufficient to maintain a percentage of total premium paid out of the total premium owed equal to or greater than 95 percent of the net monthly premium amount owed by the enrollees. If an applicant or enrollee satisfies the percentage-based premium payment threshold policy, the issuer may:

(i) Effectuate an enrollment based on payment of the binder payment under paragraph (e) of this section.

(ii) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(iii) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(2) Under a gross premium percentage-based premium payment threshold policy, issuers can consider enrollees to have paid all amounts due for the following purposes, if the enrollees pay an amount sufficient to maintain a percentage of the gross premium of the policy before the application of advance payments of the premium tax credit that is equal to or greater than 99 percent of the gross monthly premium owed by the enrollees. If an enrollee satisfies the gross premium percentage-based premium payment threshold policy, the issuer may:

(i) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(ii) Avoid terminating the enrollment for non-payment of premium as,

described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(3) Under a fixed-dollar premium payment threshold policy, issuers can consider enrollees to have paid all amounts due for the following purposes, if the enrollees pay an amount that is less than the total premium owed, the unpaid remainder of which is equal to or less than a fixed-dollar amount of $5 or less, adjusted for inflation, as prescribed by the issuer. If an enrollee satisfies the fixed-dollar premium payment threshold policy, the issuer may:

(i) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(ii) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

* * * * *

■ 5. Section 155.505 is amended by revising paragraph (b) introductory text to read as follows:

§ 155.505 General Eligibility Appeals Requirements.

* * * * *

(b) *Right to appeal.* An applicant, enrollee, or application filer must have the right to appeal.

* * * * *

■ 6. Section 155.1000 is amended by adding paragraph (e) to read as follows:

§ 155.1000 Certification standards for QHPs.

* * * * *

(e) *Denial of certification.* The Exchange may deny certification to any plan that does not meet the general certification criteria under § 155.1000(c).

■ 7. Section 155.1090 is amended by revising the section heading, the paragraph (a) heading, and paragraphs (a)(2) and (3) to read as follows:

§ 155.1090 Request for the reconsideration of a denial of certification.

(a) *Request for the reconsideration of a denial of certification specific to a Federally-facilitated Exchange*—

* * * * *

(2) *Form and manner of request.* An issuer submitting a request for reconsideration under paragraph (a)(1) of this section must submit a written request for reconsideration to HHS, in the form and manner specified by HHS, within 7 calendar days of the date of the written notice of denial of certification. The issuer must include any and all documentation the issuer wishes to provide in support of its request with its request for reconsideration. The request for reconsideration must provide clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error.

(3) *HHS reconsideration decision.* HHS will review the reconsideration request to determine whether the issuer's reconsideration request provided clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error. HHS will provide the issuer with a written notice of the reconsideration decision. The decision will constitute HHS' final determination.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 8. The authority citation for part 156 continues 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.

■ 9. Section 156.201 is amended by adding paragraph (c) to read as follows:

§ 156.201 Standardized plan options.

* * * * *

(c) For PY 2026 and subsequent plan years, an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies. For the purposes of this standard, a standardized plan option with a different product, provider network, and/or formulary ID would be considered meaningfully different.

■ 10. Section 156.202 is amended by revising paragraph (b) and paragraph (d) introductory text to read as follows:

§ 156.202 Non-standardized plan option limits.

* * * * *

(b) For plan year 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of this section), in any service area.

* * * * *

(d) For plan year 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of this section), and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in the issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage, and service area.

* * * * *

■ 11. Section 156.1220 is amended by adding paragraph (a)(2)(i) and reserved paragraph (a)(2)(ii) to read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(2) * * *

(i) Notwithstanding paragraph (a)(1) and (2) of this section, for appeals related to HHS–RADV under paragraphs (a)(1)(vii) and (viii) of this section, HHS will only take action to adjust risk adjustment State payments and charges for an issuer in response to an appeal decision when the impact of the decision to the filer's HHS–RADV adjustments to risk adjustment State transfers is greater than or equal to $10,000.

(ii) [Reserved]

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 12. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 13. Section 158.103 is amended by adding a definition for ''Qualifying issuer'' in alphabetical order to read as follows:

§ 158.103 Definitions.

* * * * *

Qualifying issuer means an issuer whose ratio of net payments related to

the risk adjustment program under section 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18063, to earned premiums prior to accounting for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs (as described in § 158.130(b)(5)) in a relevant State and market is greater than or equal to 50 percent.

* * * * *

■ 14. Section 158.140 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(4) * * *

(ii) Beginning with the 2026 MLR reporting year, for qualifying issuers (as defined in § 158.103), receipts related to the transitional reinsurance program and net payments or receipts related to the risk corridors program (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341 and 1342 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062. For all other issuers, receipts related to the transitional reinsurance program and net payments or receipts related to the risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

* * * * *

■ 15. Section 158.240 is amended by revising paragraph (c)(2) and adding paragraph (c)(3) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) * * *

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to the reinsurance, risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent). If the issuer is not a qualifying issuer (defined in § 158.103), the issuer's total earned premium for the MLR reporting year in the individual market in the State is $200,000, incurred claims are $121,250, the issuer received transitional reinsurance payments of $2,500, and made net payments related to risk adjustment and risk corridors of $20,000 (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), then the issuer's gross earned premium in the individual market in the State would be $200,000 plus $2,500 minus $20,000, for a total of $182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1), and 158.162(b)(1), allocated to the individual market in the State are $15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240, are $17,500 ($20,000 reduced by $2,500), then the issuer would subtract $15,000 and add $17,500 to gross premium revenue of $182,500, for a base of $185,000 in adjusted premium. The issuer would owe rebates of 5 percent of $185,000, or $9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid $2,000 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or $92.50.

(3) As another example, if an issuer is a qualifying issuer (defined in § 158.103), the issuer's total earned premium for the MLR reporting year in the individual market in the State is $90,000, incurred claims are $151,250, and the issuer received transitional reinsurance payments of $12,500 and net receipts related to risk adjustment of $110,000, then the issuer's gross earned premium in the individual market in the State would be $90,000 plus $12,500, for a total of $102,500. If the qualifying issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1), and 158.162(b)(1), allocated to the individual market in the State are $15,000, and the reinsurance payments that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240 are $12,500, then the qualifying issuer would subtract $15,000 and $12,500 from gross premium revenue of $102,500, for a subtotal of $75,000. The qualifying issuer would then add $110,000 in net receipts related to risk adjustment, for a base of $185,000 in adjusted premium. The qualifying issuer would owe rebates of 5 percent of $185,000, or $9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid $900 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or $92.50.

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Dated: October 2, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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